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(54) **PATIENT INTERFACE**

(75) Inventors: **Memduh Guney**, Killara (AU); **Rupert Christian Scheiner**, Davidson (AU); **David Anthony Pidcock**, Baulkham Hills (AU); **Gerard Michael Rummery**, Linden (AU); **Matthew Eves**, Carlingford (AU); **Craig David Edwards**, Annandale (AU); **Melanie Lucia Cariola**, Epping (AU); **Muditha Pradeep Dantanarayana**, Cherrybrook (AU); **Michael Chen**, Bella Vista (AU); **Christopher Scott Skipper**, North Ryde (AU); **Karthikeyan Selvarajan**, Gosford (AU); **Steven John Lubke**, Stanmore (AU); **Bruce David Gregory**, Leichhardt (AU); **Joel Edward Gibson**, Balmain (AU); **Andrew David Cameron**, Picnic Point (AU); **Philip Rodney Kwok**, Chatswood (AU)

(73) Assignee: **ResMed Limited**, Bella Vista (AU)

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See application file for complete search history.

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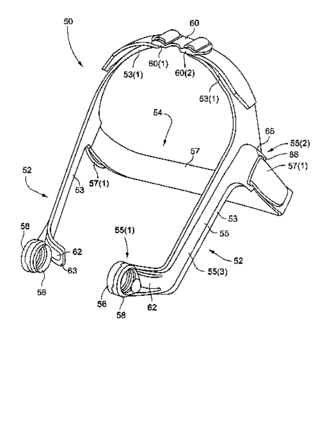
Primary Examiner — Tan-Uyen (Jackie) T Ho
Assistant Examiner — Eric Bryant
(74) *Attorney, Agent, or Firm* — Nixon & Vanderhye P.C.

(57) **ABSTRACT**

A patient interface for delivering breathable gas to a patient includes a nasal prong assembly including a pair of nasal prongs structured to sealingly communicate with nasal passages of a patient's nose in use and headgear to maintain the nasal prong assembly in a desired position on the patient's face. The headgear includes side straps and rigidizers provided to respective side straps. Each rigidizer includes a first end portion that provides a connector structured to engage a respective end of the nasal prong assembly and an inwardly curved protrusion in the form of a cheek support that curves inwardly of the connector. The cheek support is adapted to follow the contour of the patient's cheek and guide a respective end portion of the side strap into engagement with the patient's cheek to provide a stable cheek support.

34 Claims, 250 Drawing Sheets



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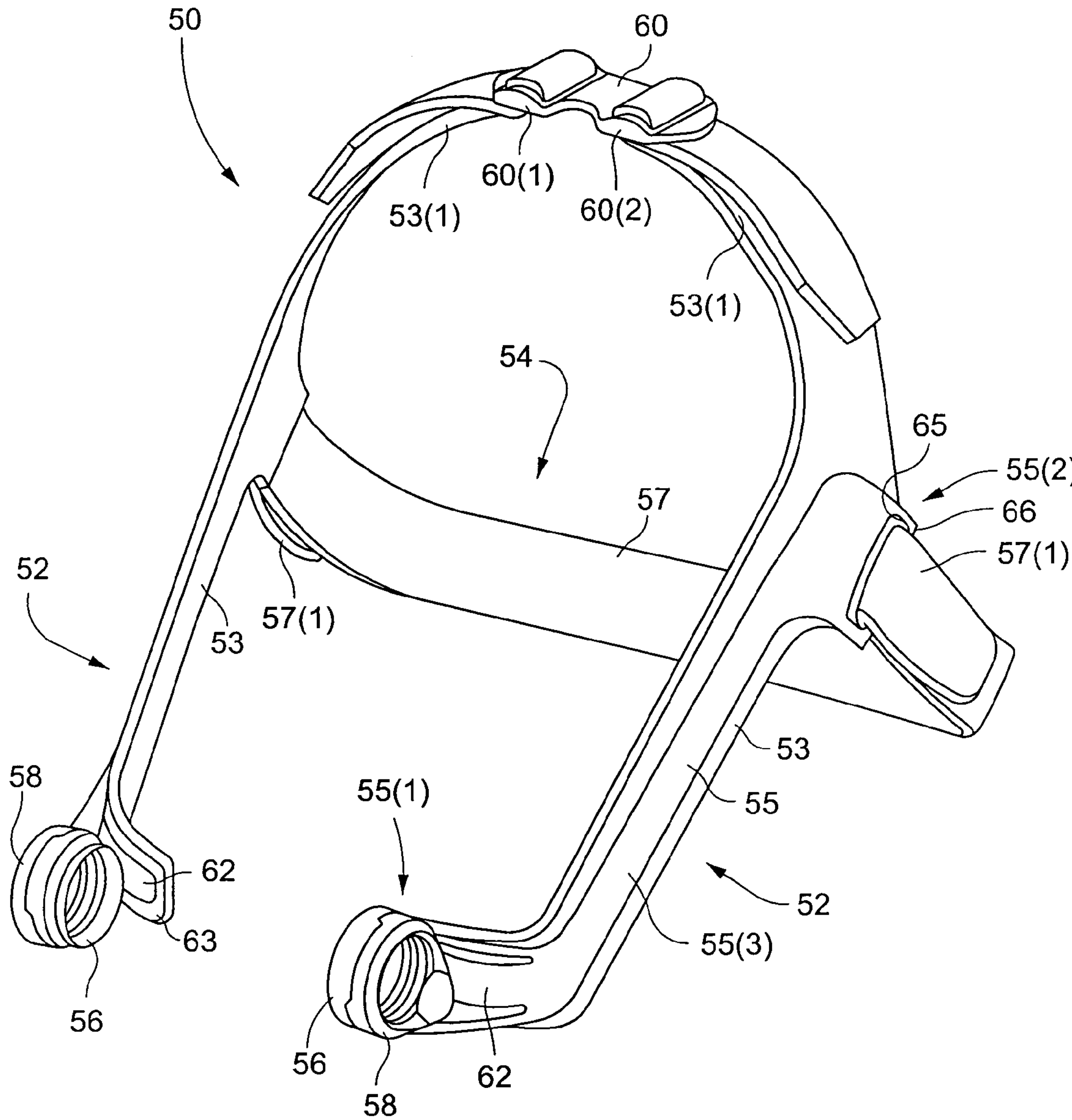
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FIG. 1-1

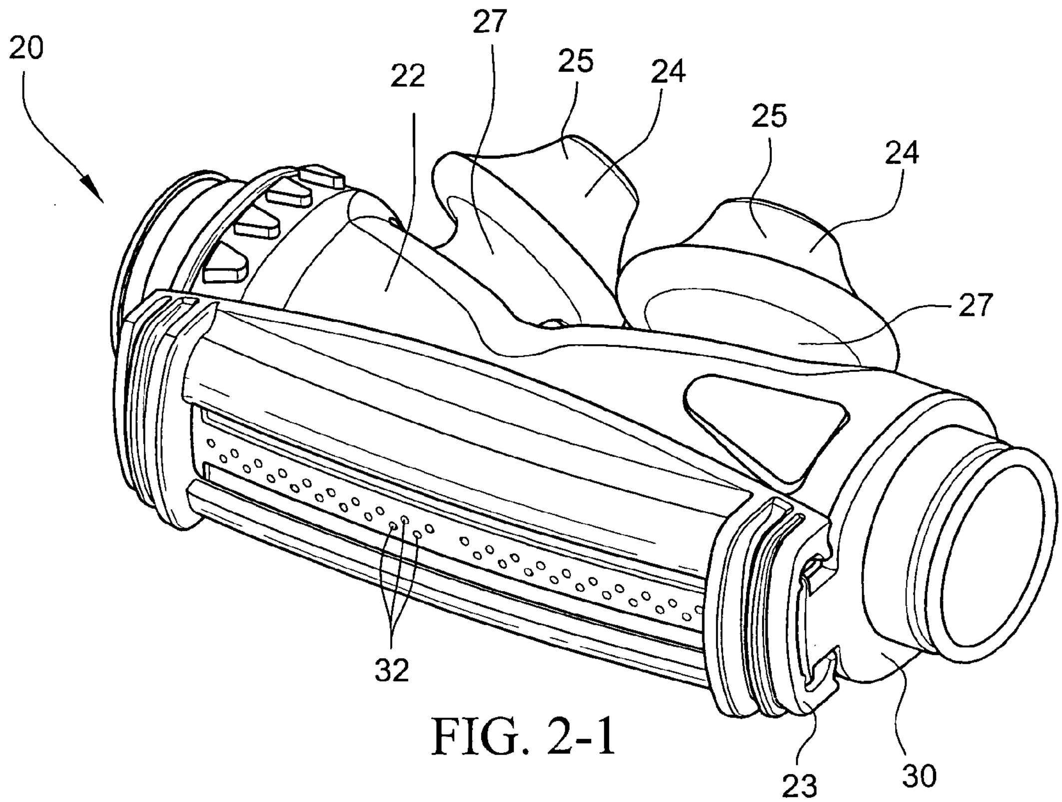


FIG. 2-1

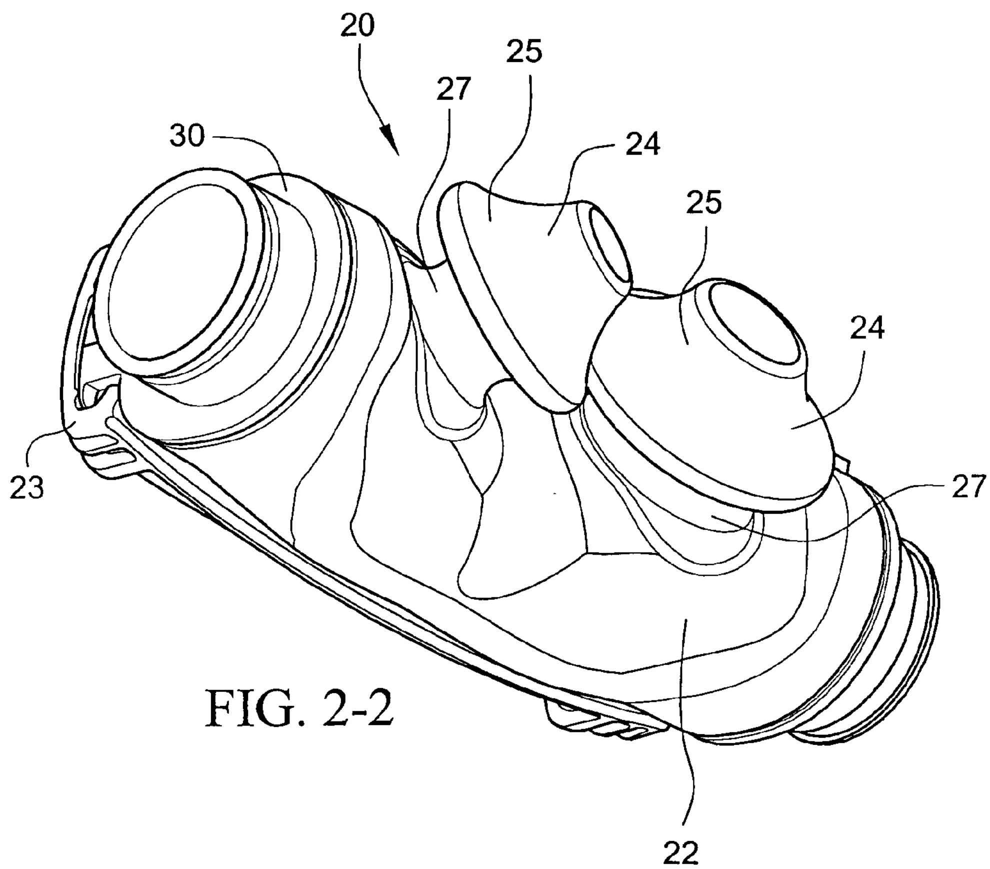


FIG. 2-2

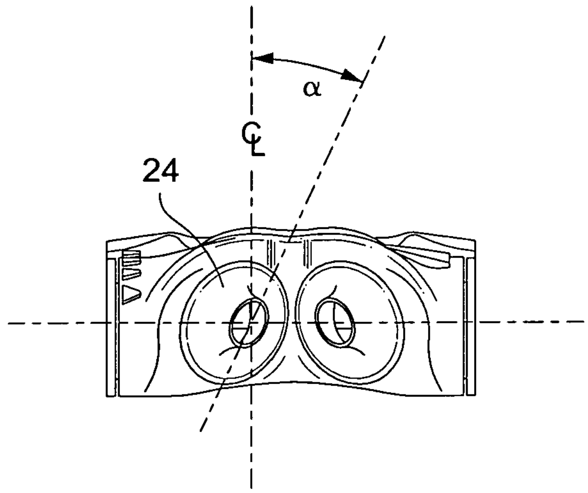


FIG. 2-3

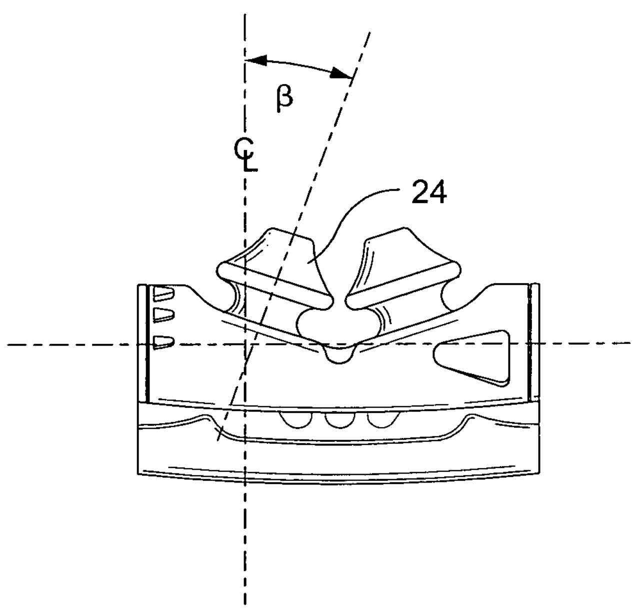


FIG. 2-4

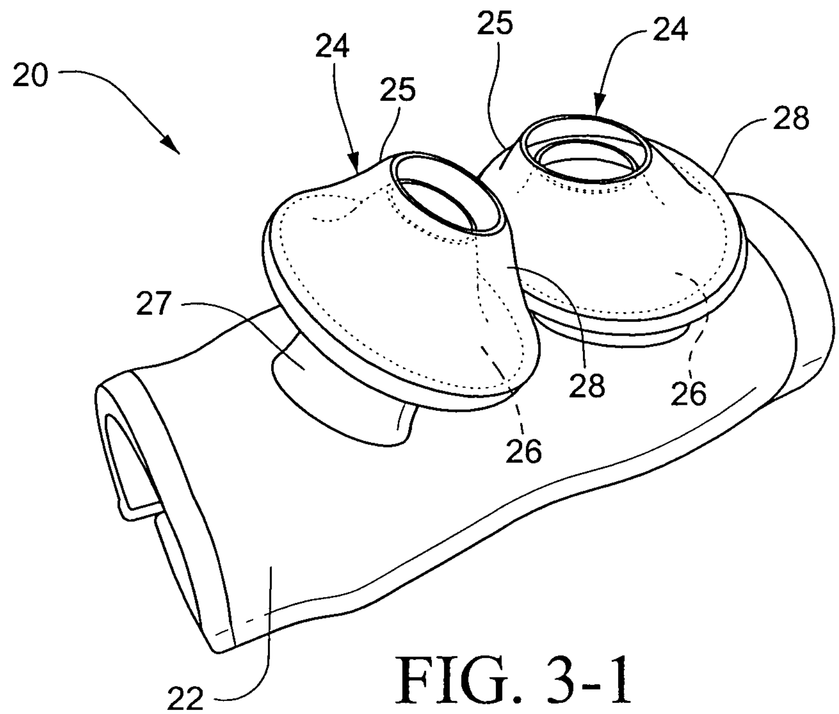


FIG. 3-1

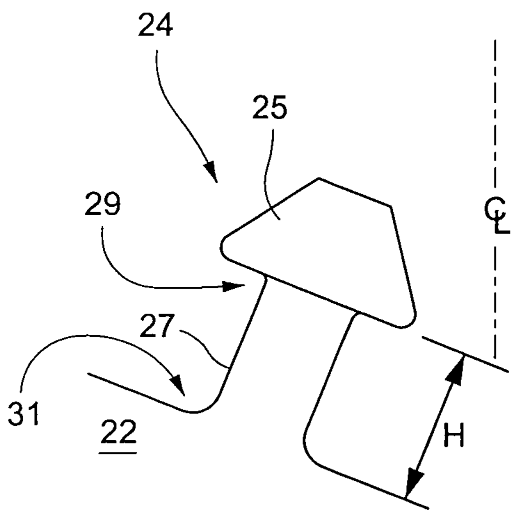


FIG. 4-1

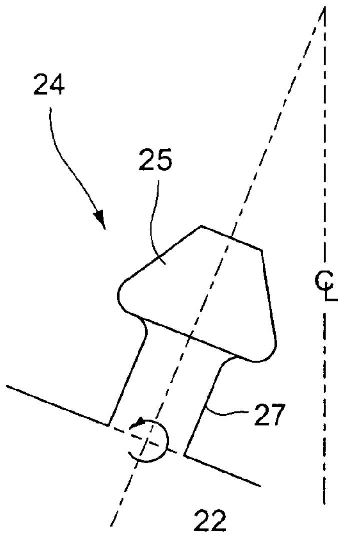


FIG. 4-2

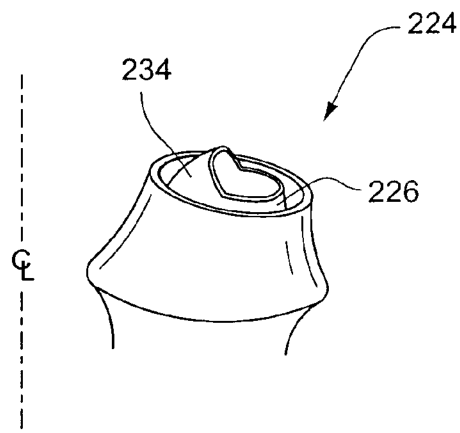


FIG. 5-1

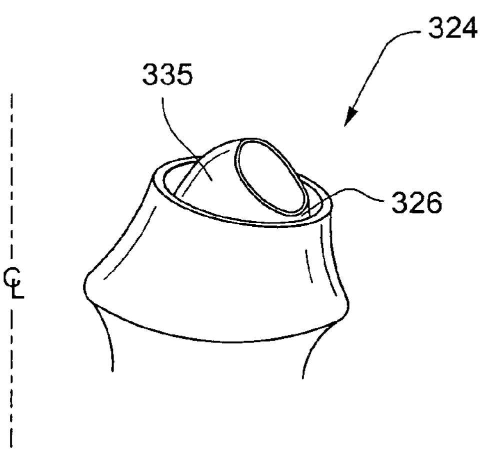


FIG. 5-2

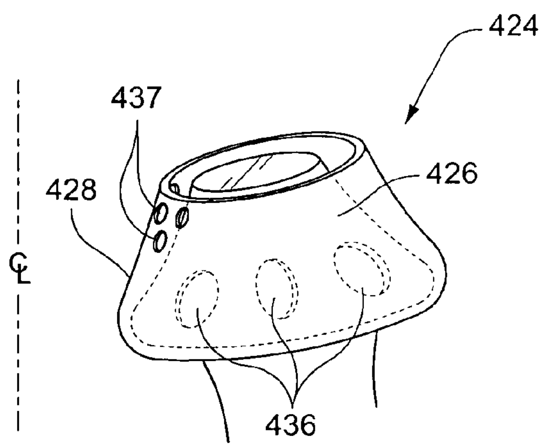


FIG. 5-3

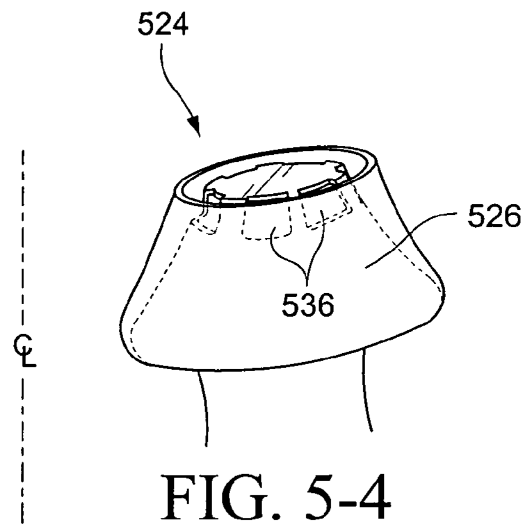


FIG. 5-4

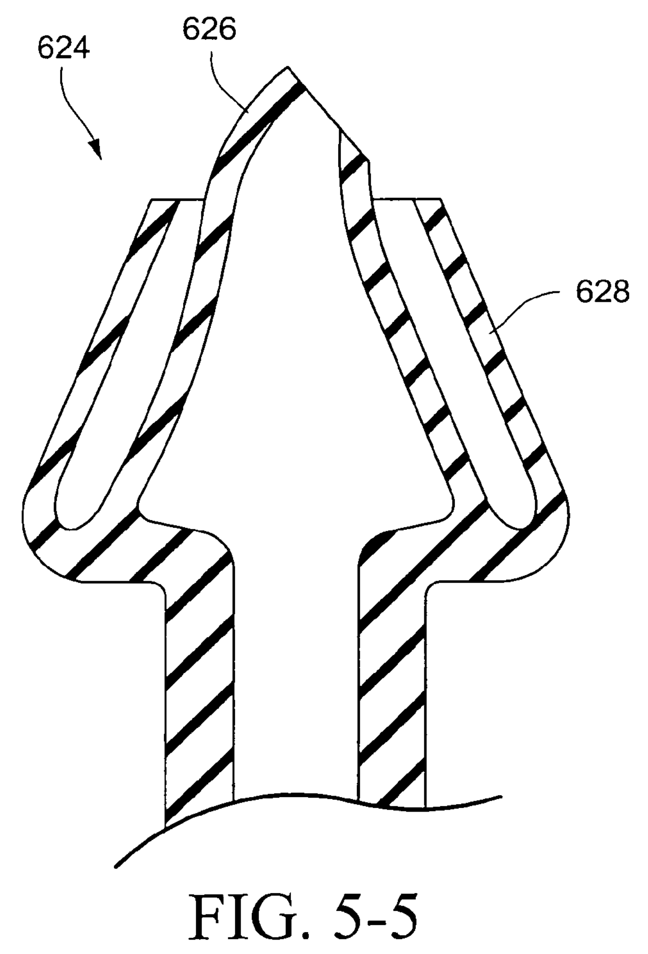


FIG. 5-5

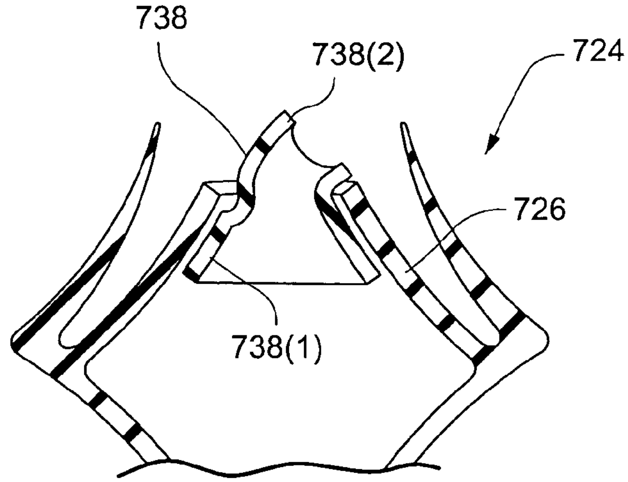


FIG. 5-6

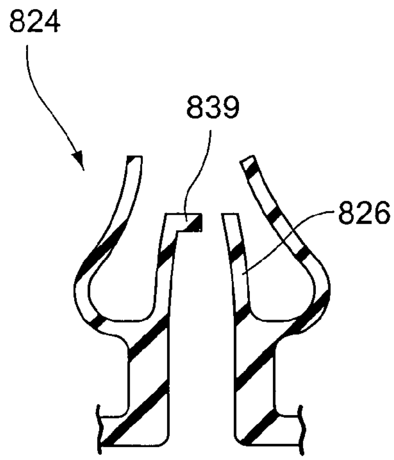


FIG. 5-7-1

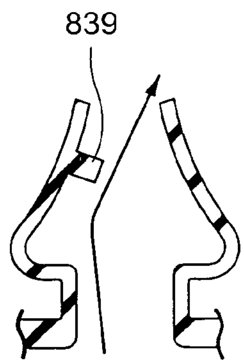


FIG. 5-7-2

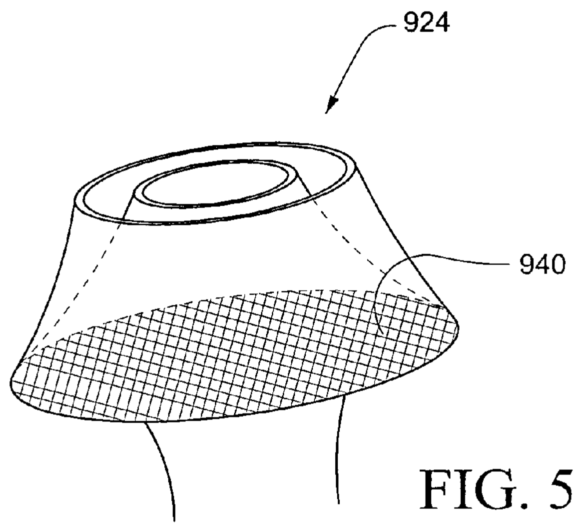


FIG. 5-8

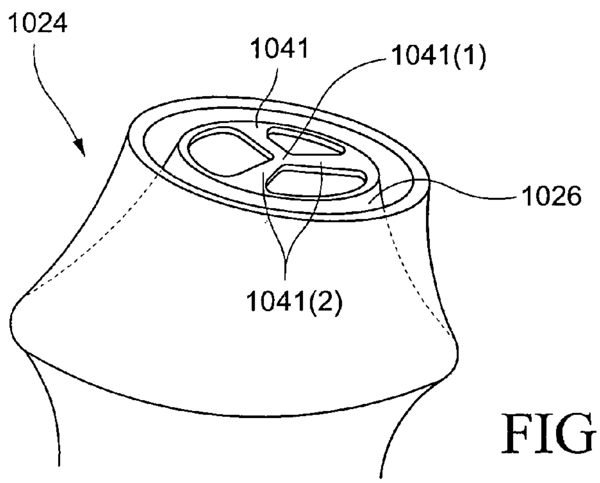


FIG. 5-9-1

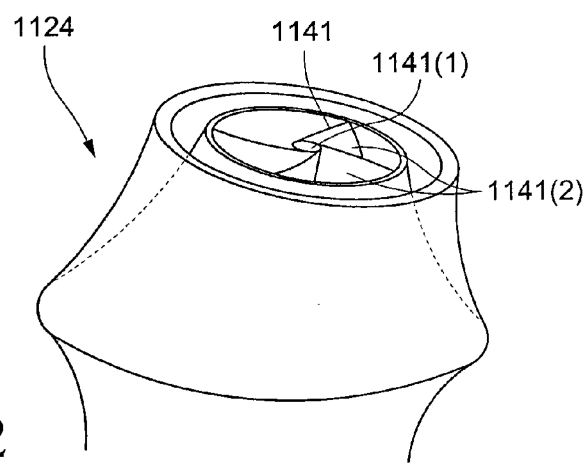


FIG. 5-9-2

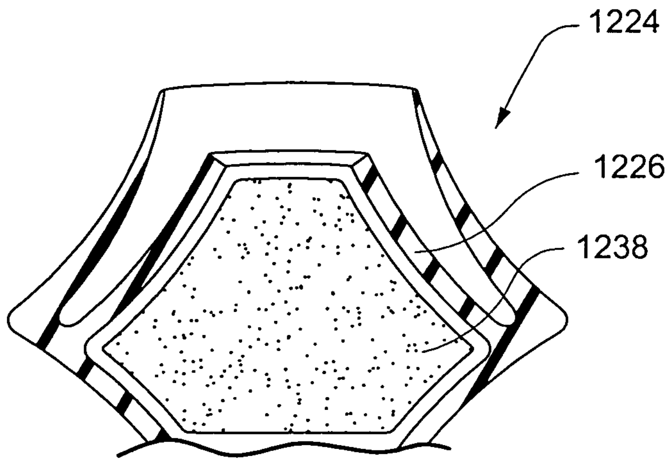


FIG. 5-10

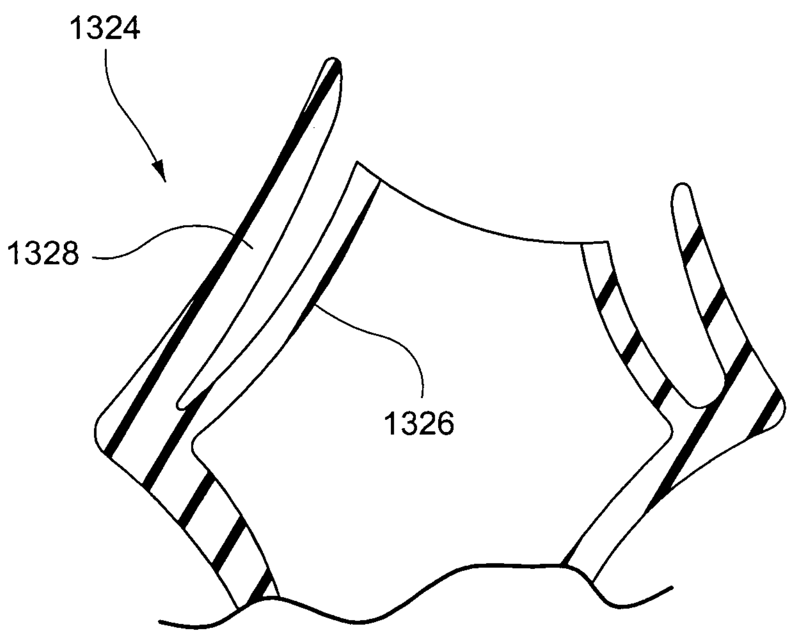
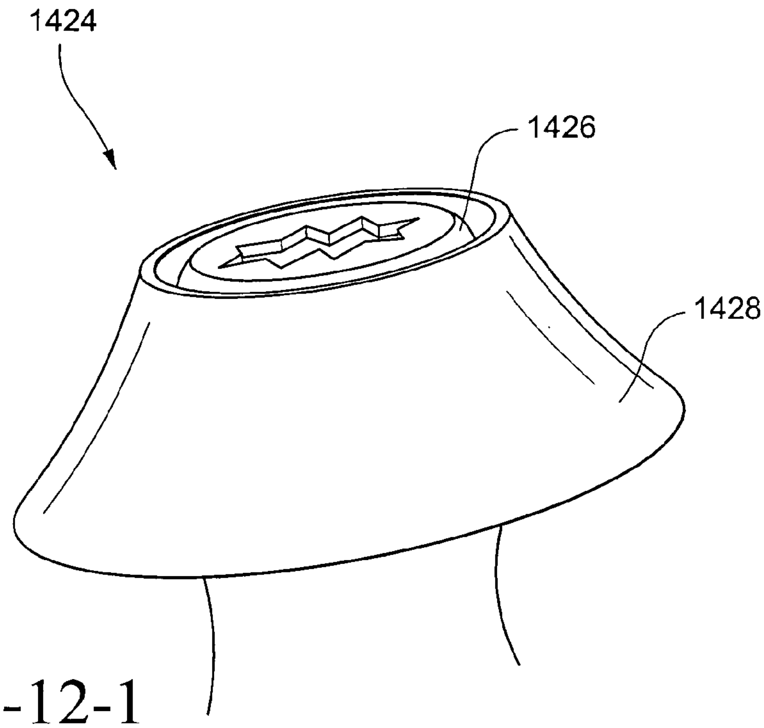


FIG. 5-11



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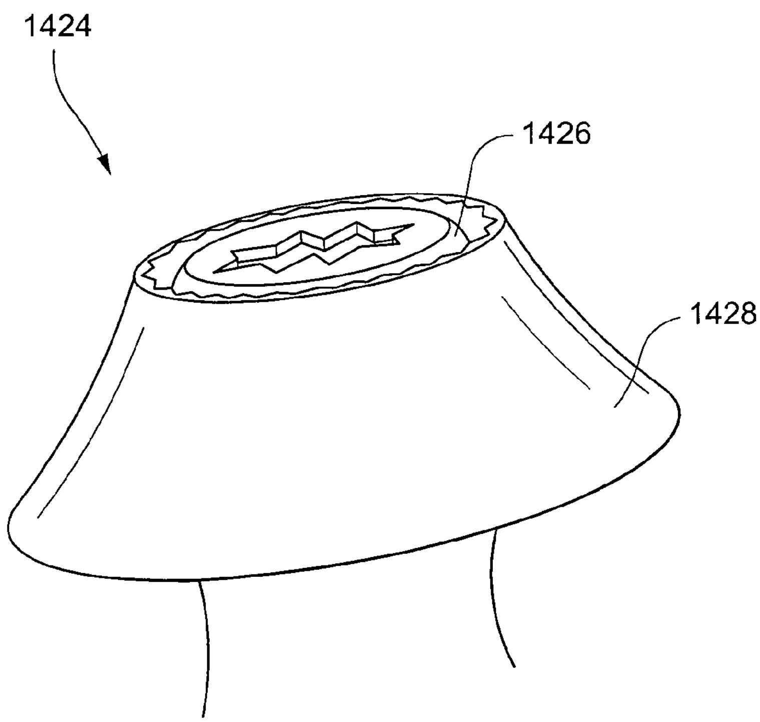

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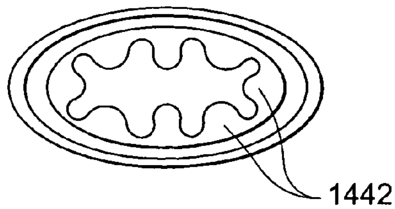

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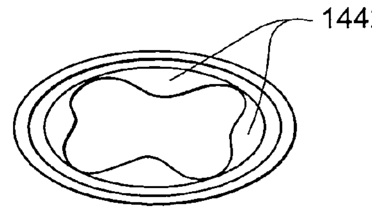

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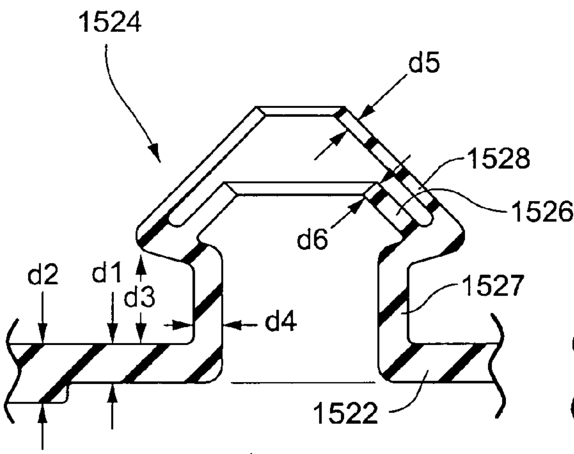
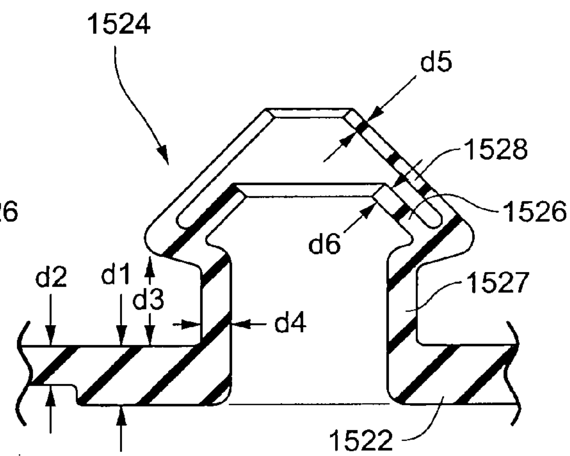


FIG. 5-13-1



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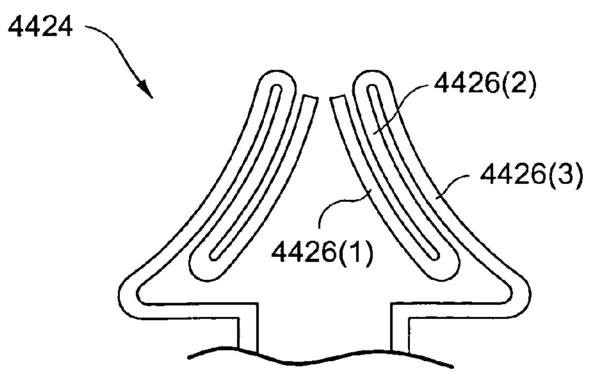

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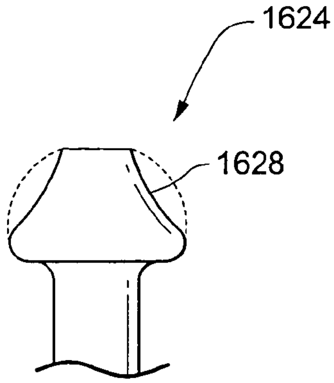

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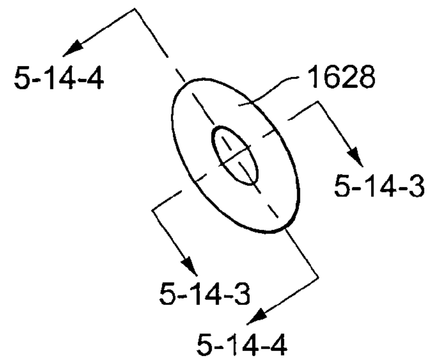

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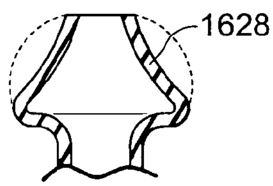

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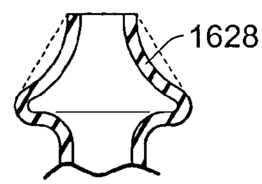

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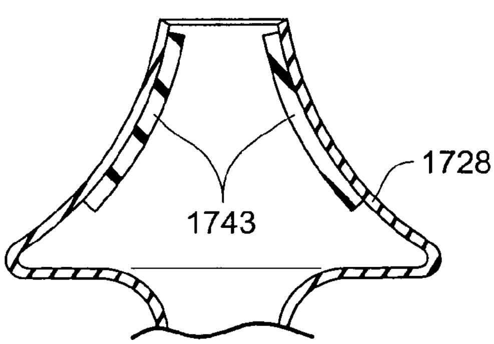

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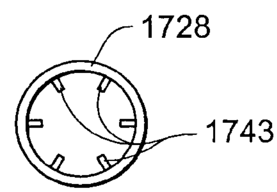

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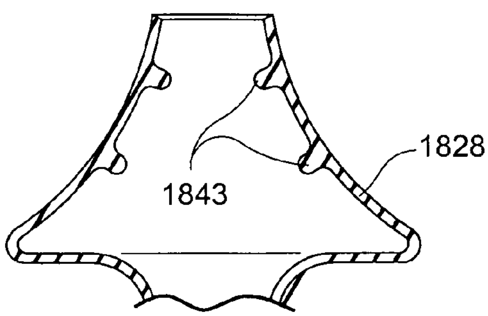

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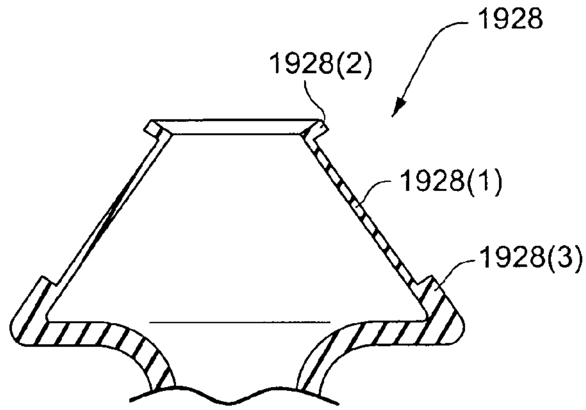

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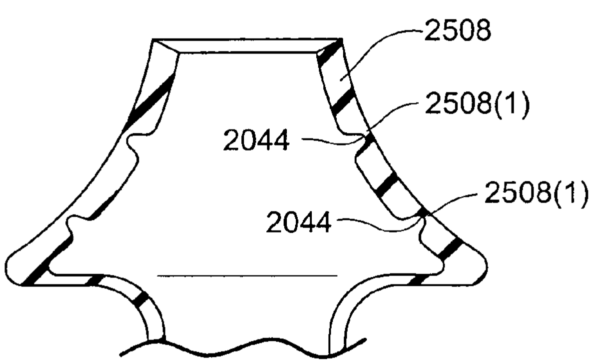

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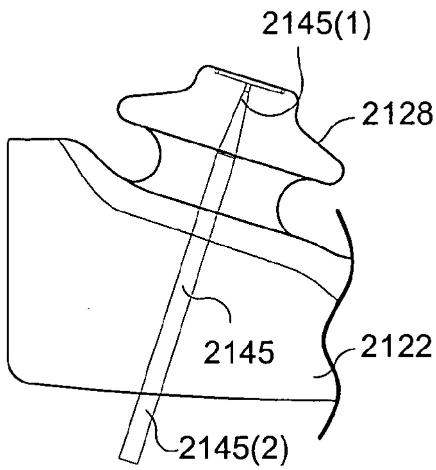

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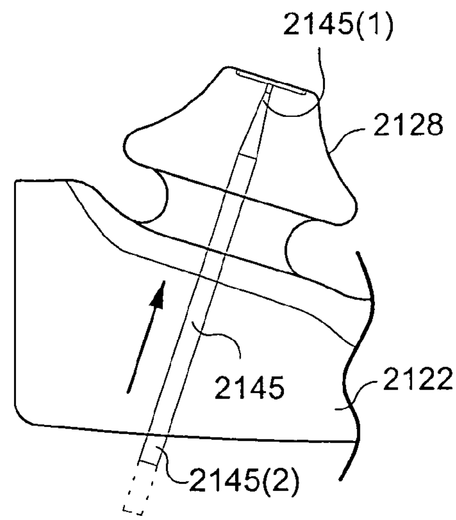


FIG. 5-19-2

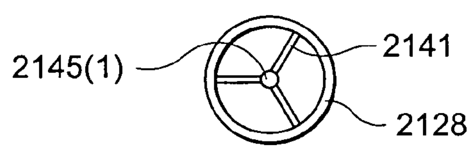


FIG. 5-19-3

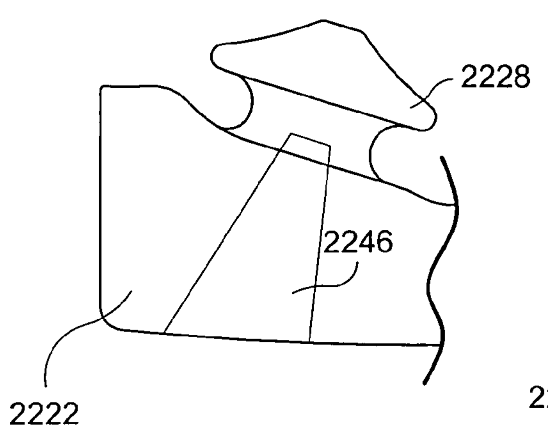


FIG. 5-20-1

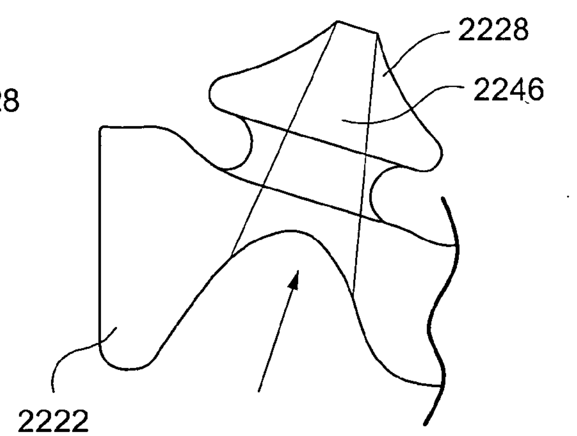


FIG. 5-20-2

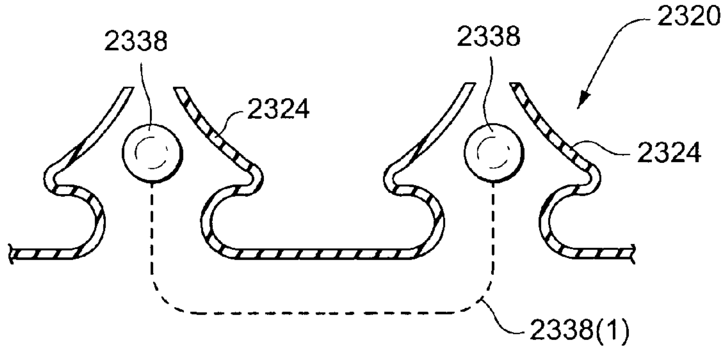


FIG. 5-21

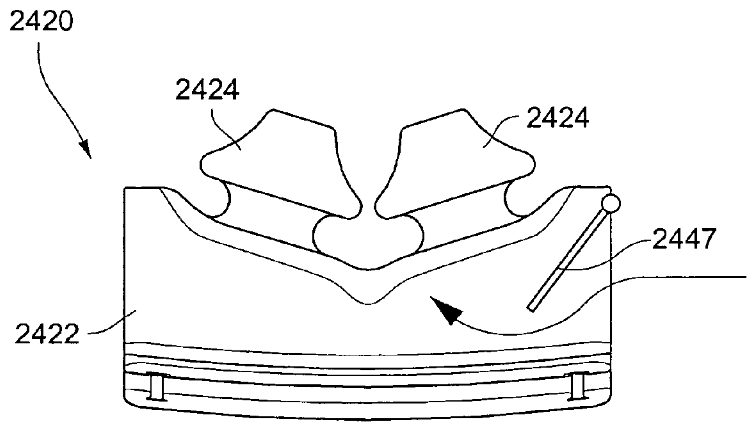


FIG. 5-22-1

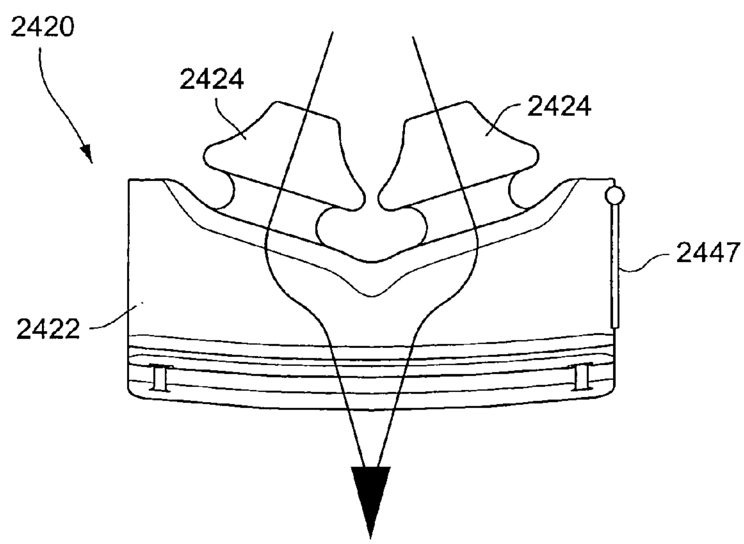


FIG. 5-22-2

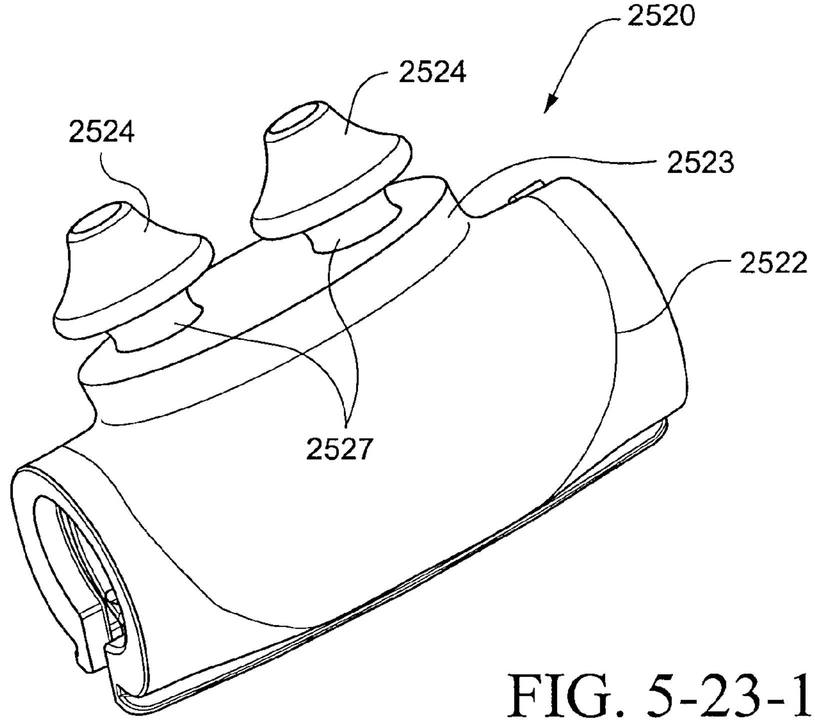


FIG. 5-23-1

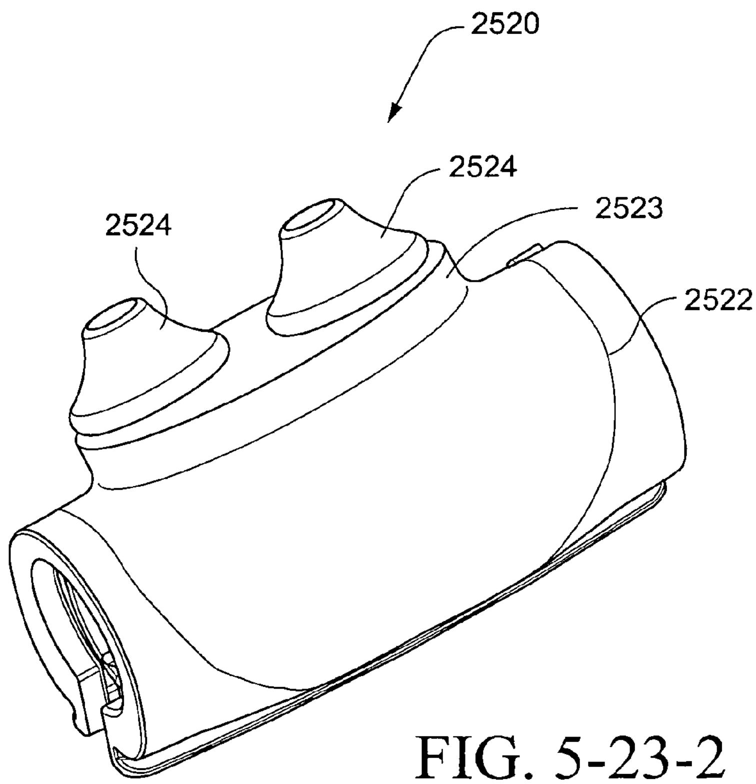


FIG. 5-23-2

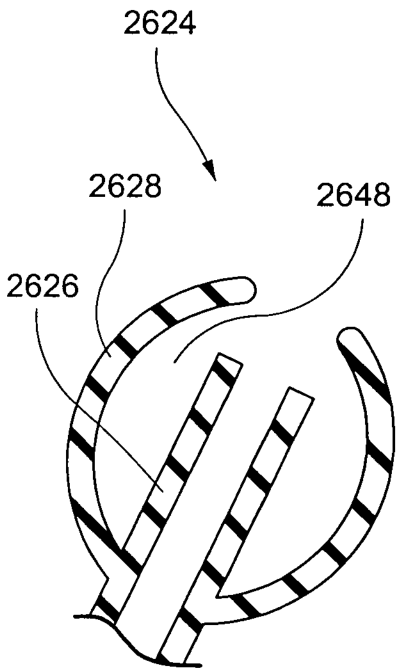


FIG. 5-24-1

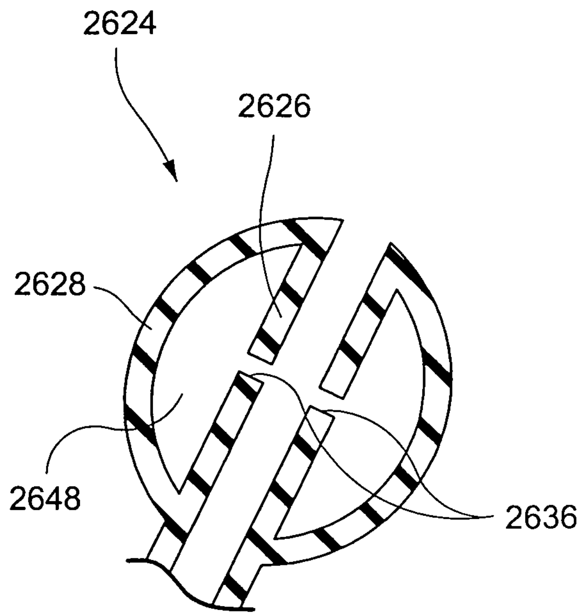


FIG. 5-24-2

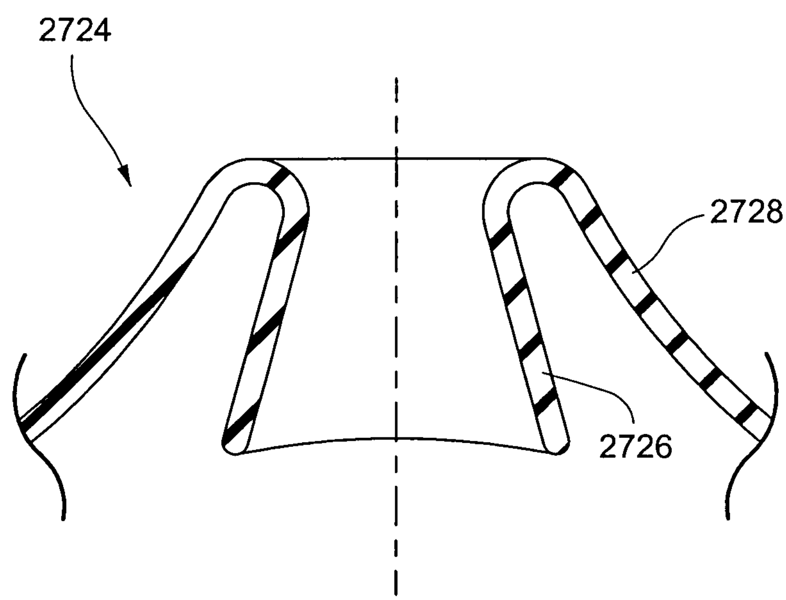


FIG. 5-25

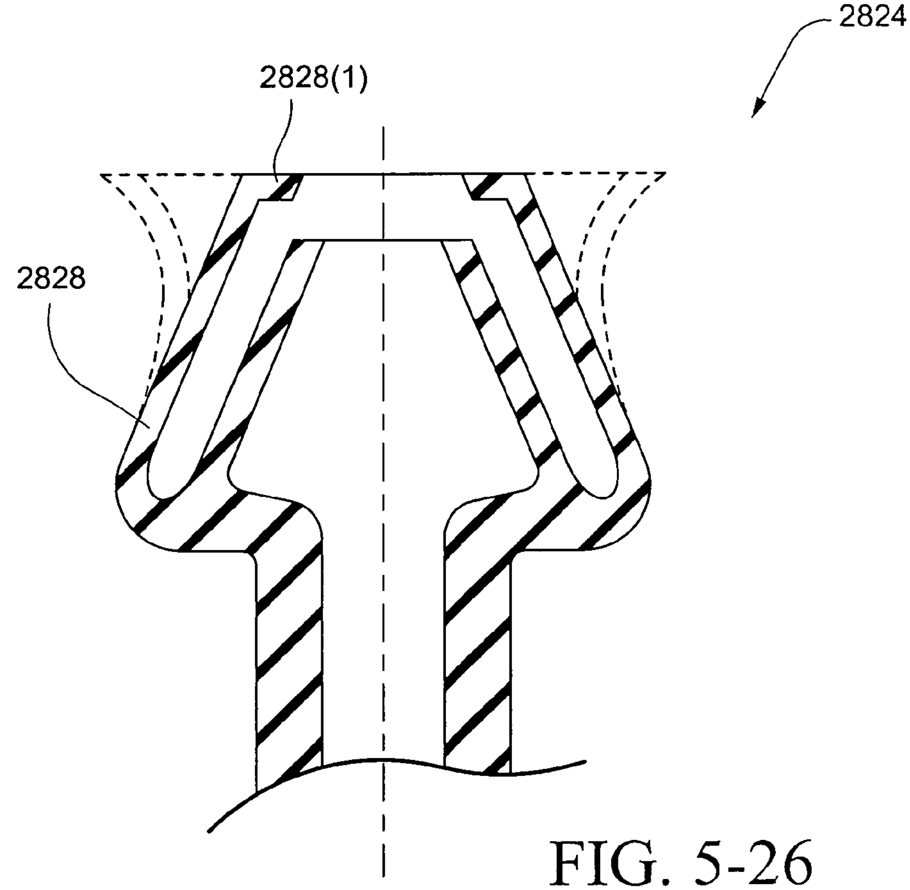


FIG. 5-26

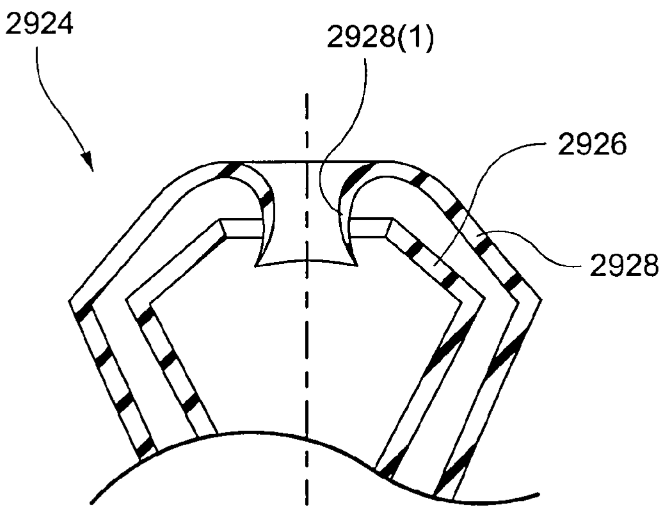


FIG. 5-27

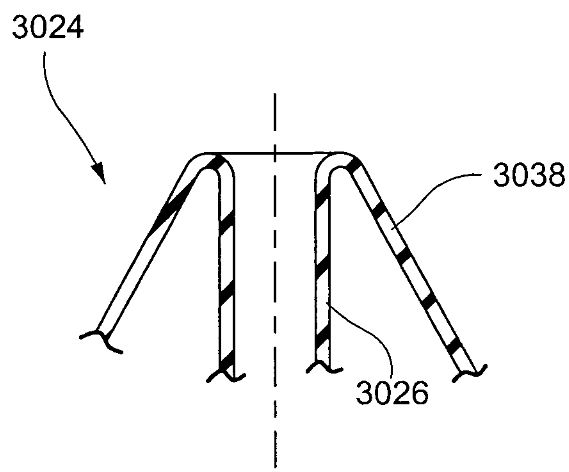


FIG. 5-28

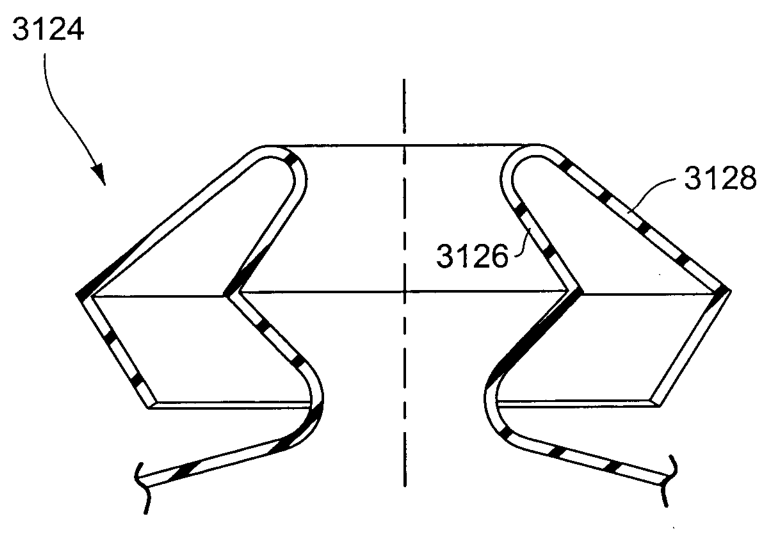


FIG. 5-29

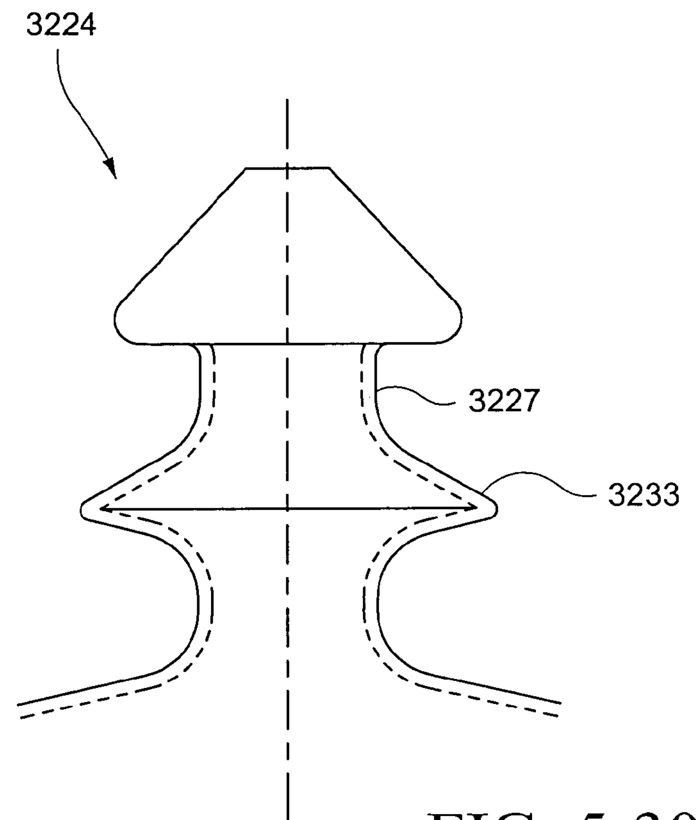


FIG. 5-30

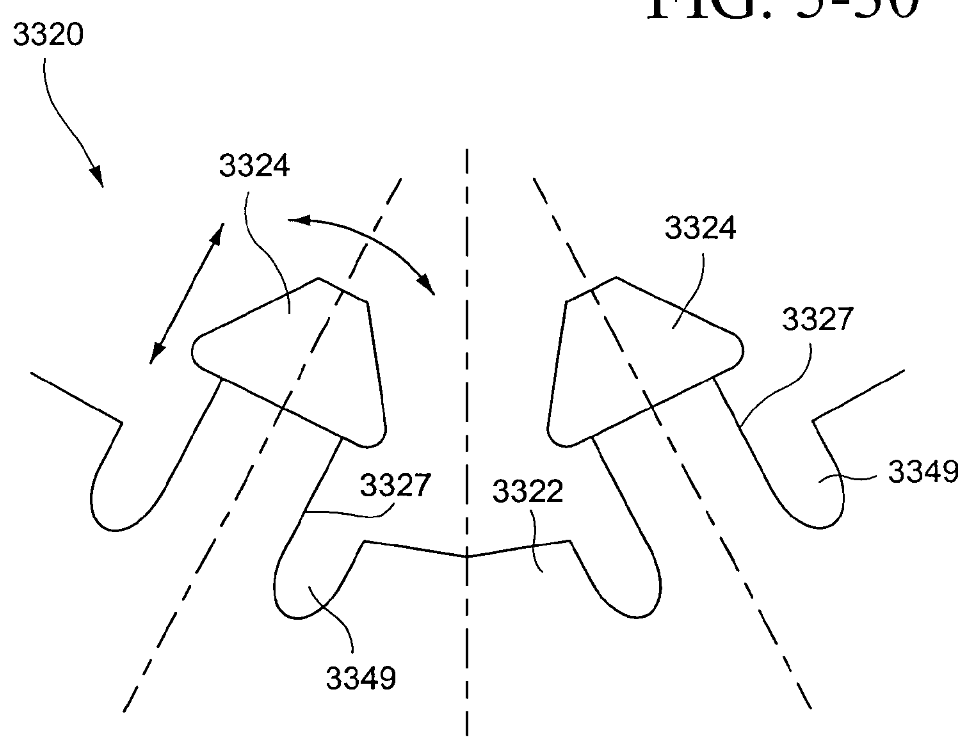


FIG. 5-31

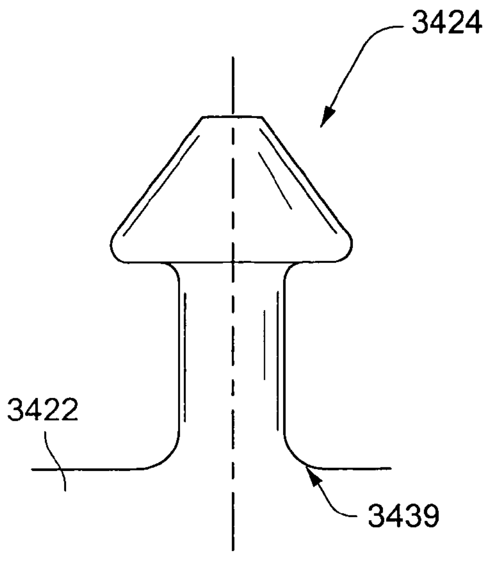


FIG. 5-32-1

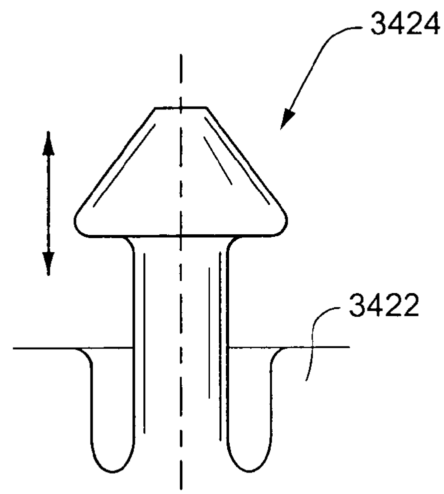


FIG. 5-32-2

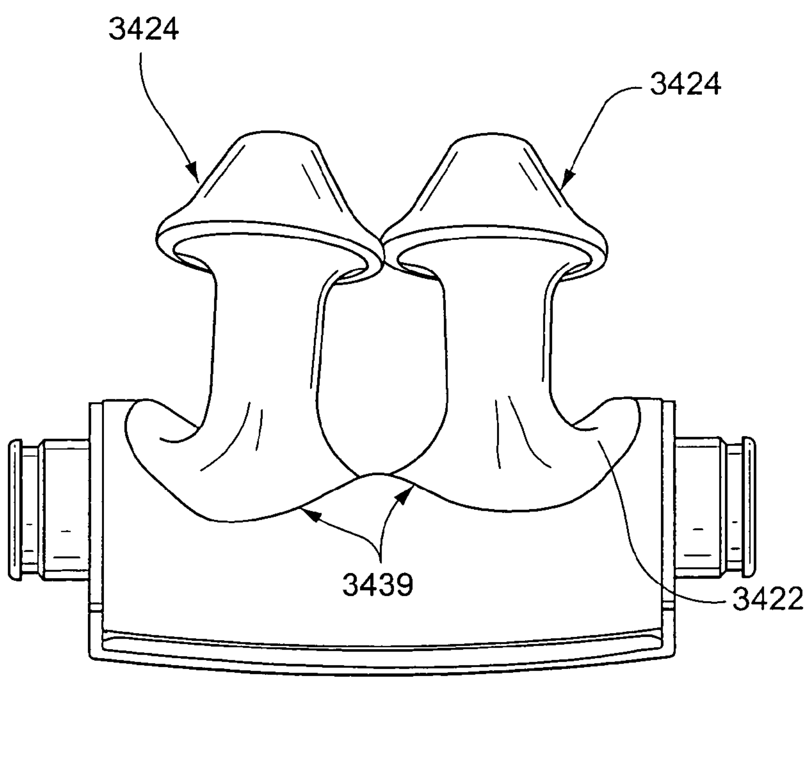


FIG. 5-32-3

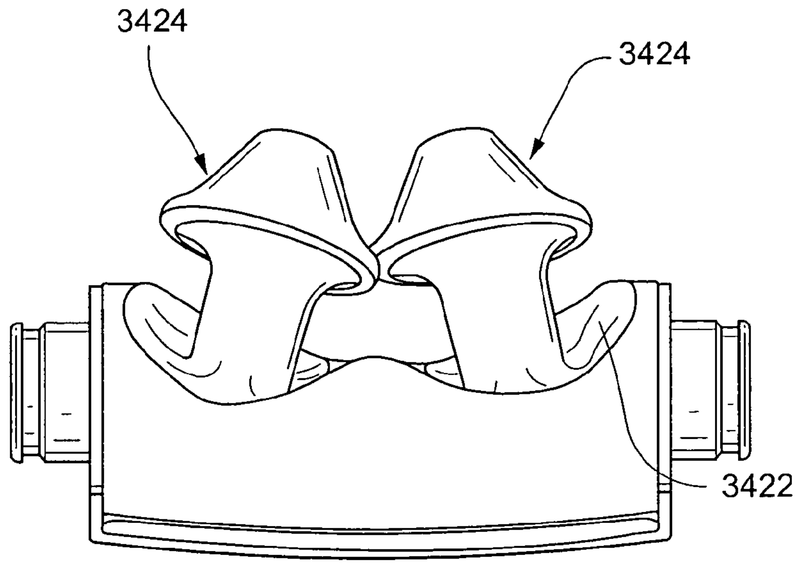


FIG. 5-32-4

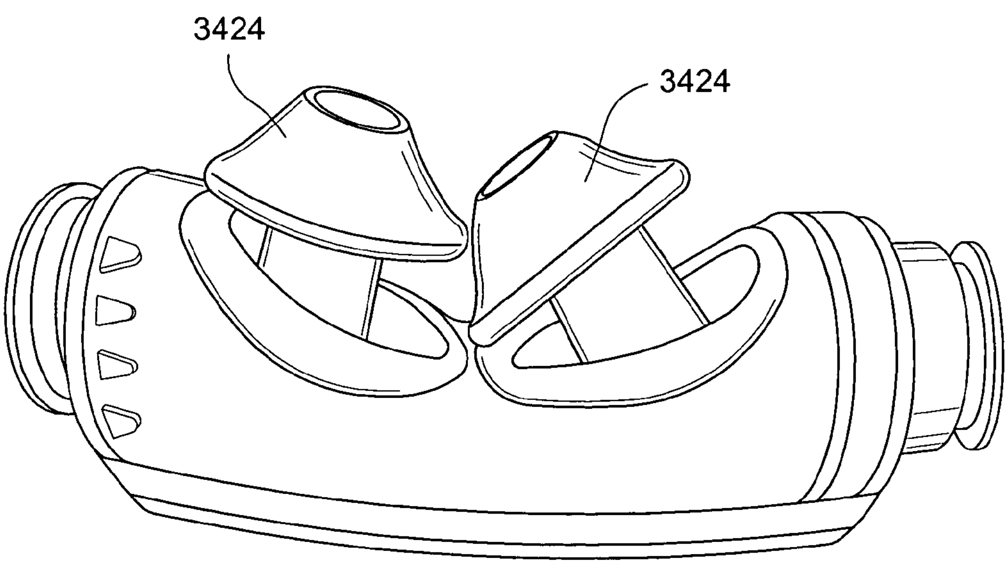


FIG. 5-32-5

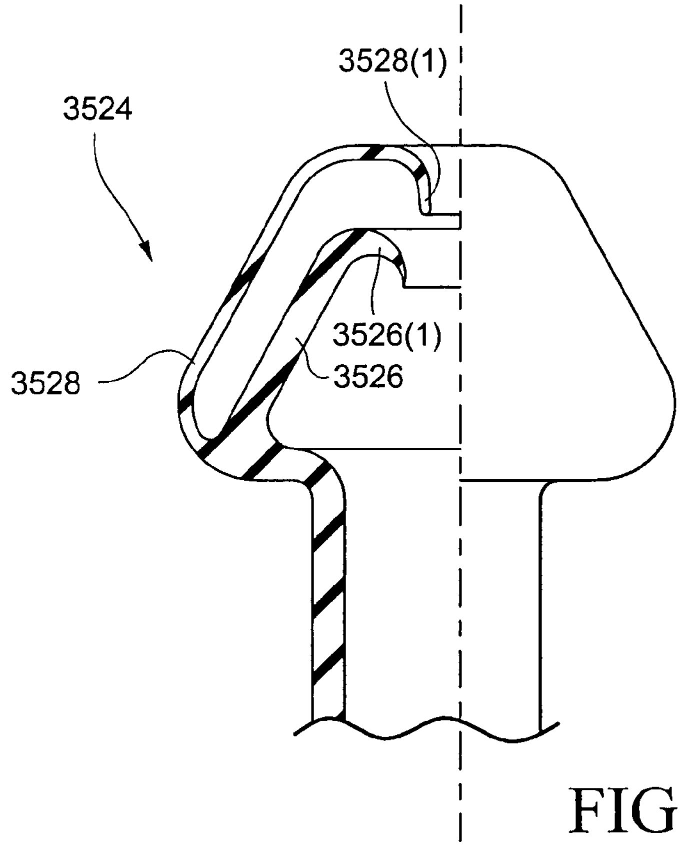


FIG. 5-33

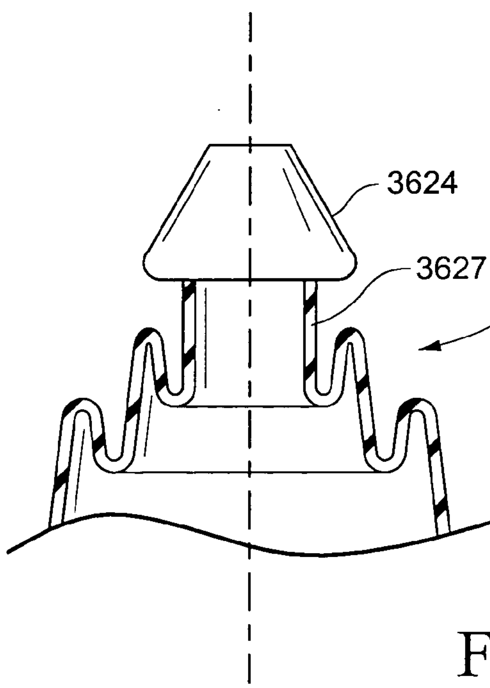


FIG. 5-34

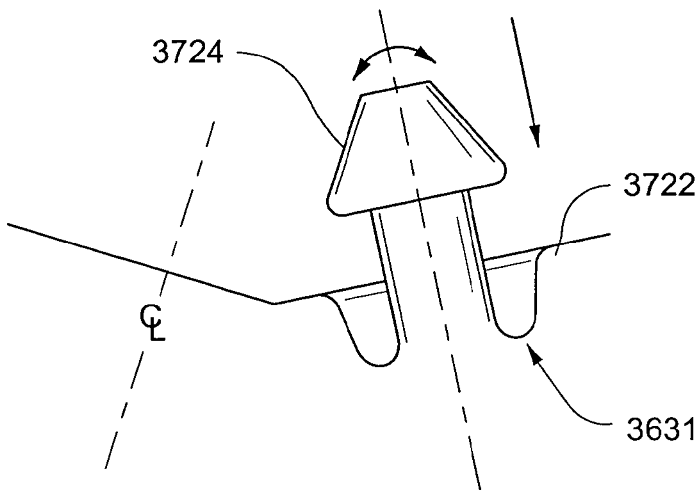


FIG. 5-35

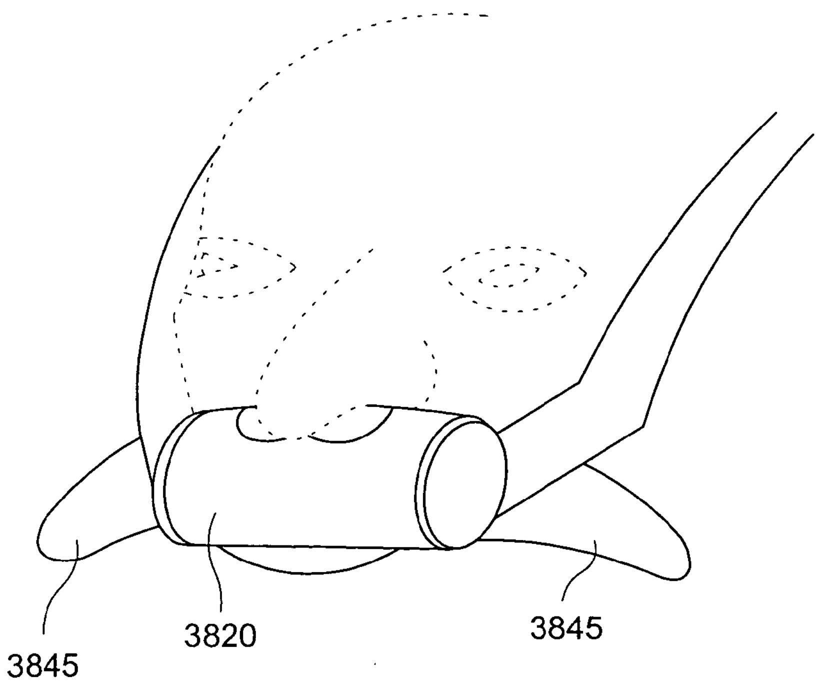


FIG. 5-36-1

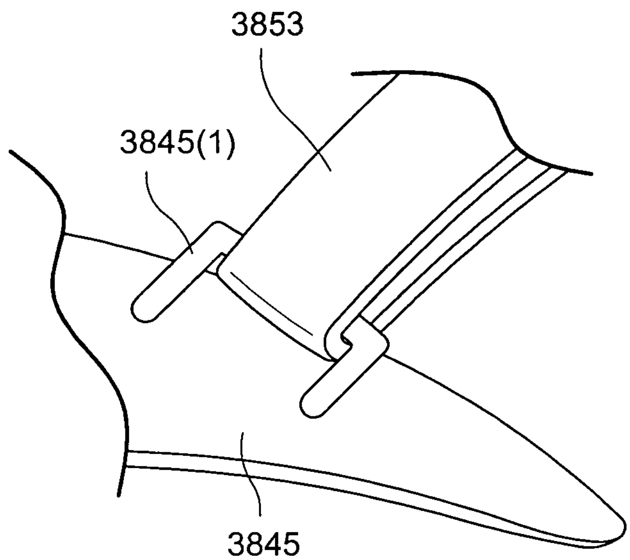


FIG. 5-36-2

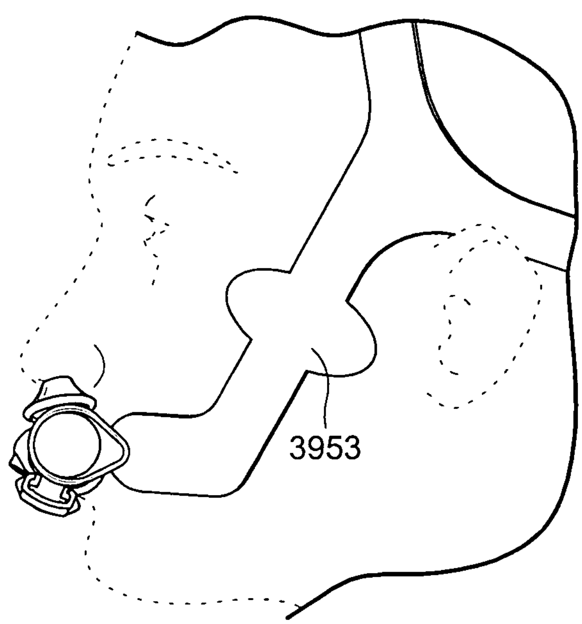


FIG. 5-37

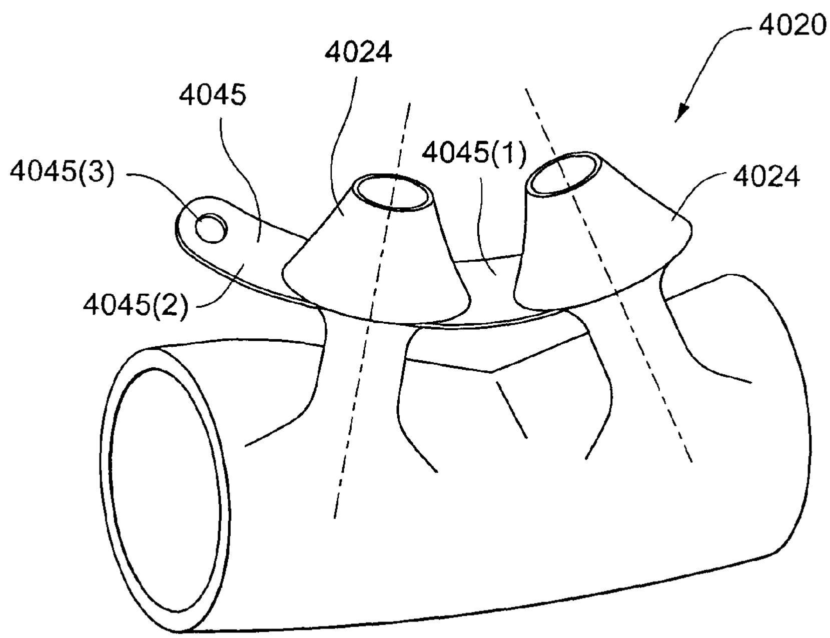


FIG. 5-38

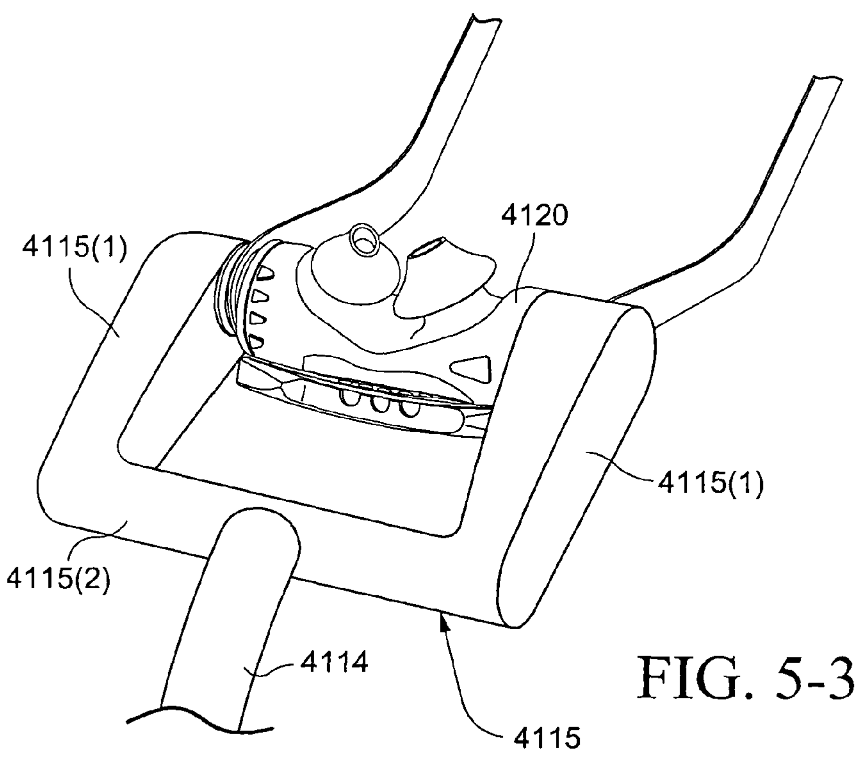


FIG. 5-39

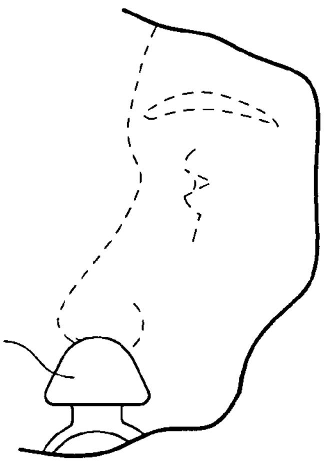


FIG. 5-40

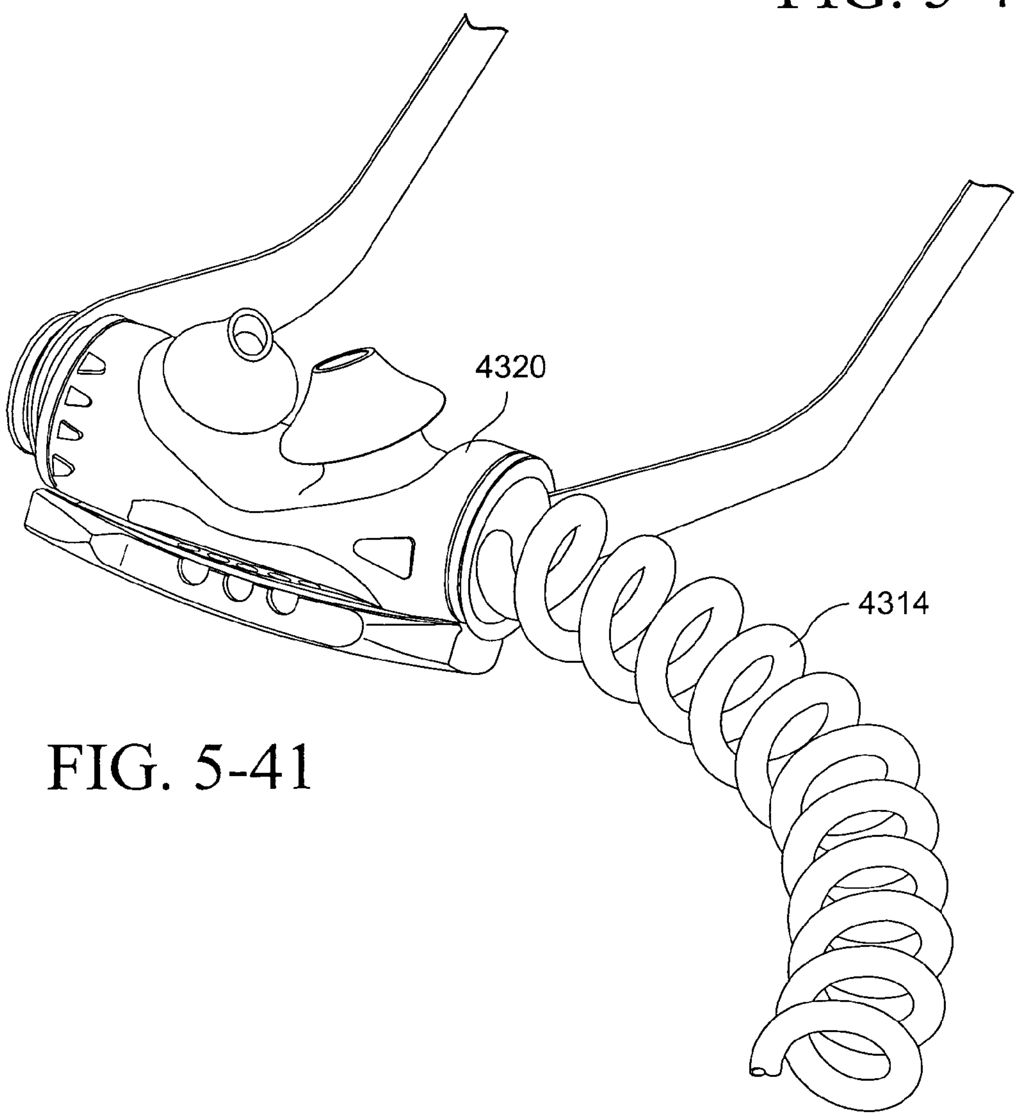


FIG. 5-41

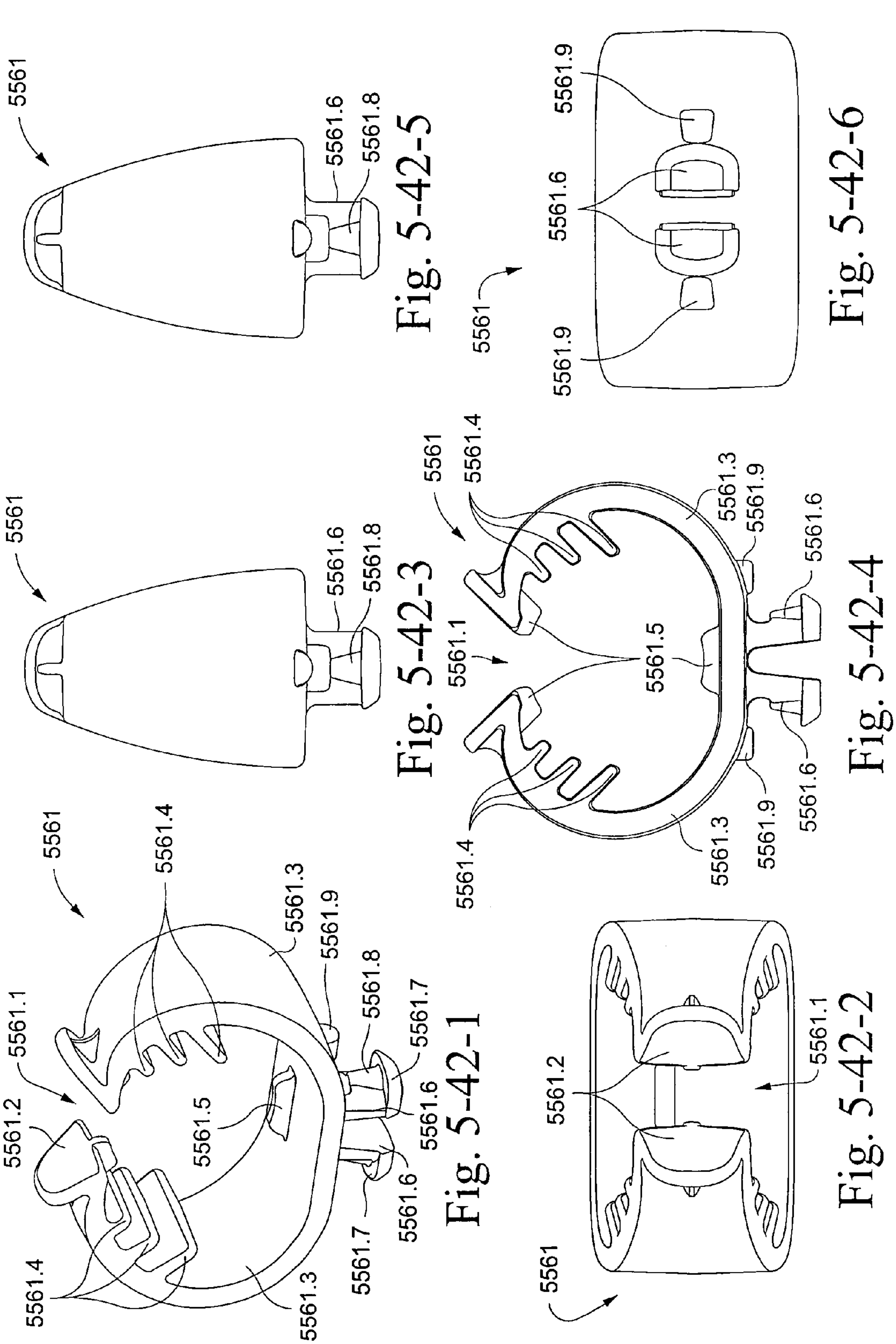


Fig. 5-42-1

Fig. 5-42-2

Fig. 5-42-3

Fig. 5-42-4

Fig. 5-42-5

Fig. 5-42-6

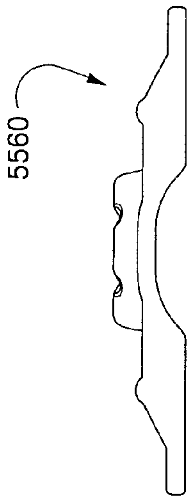


Fig. 5-43-5

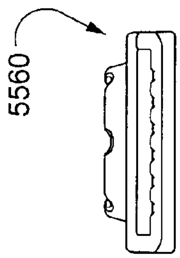


Fig. 5-43-6

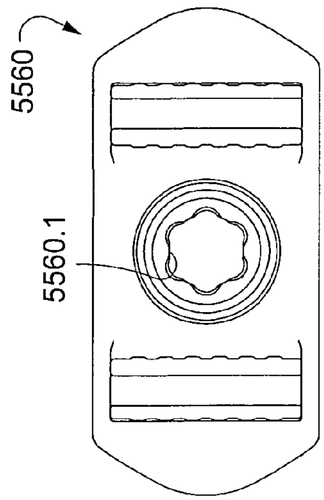


Fig. 5-43-7

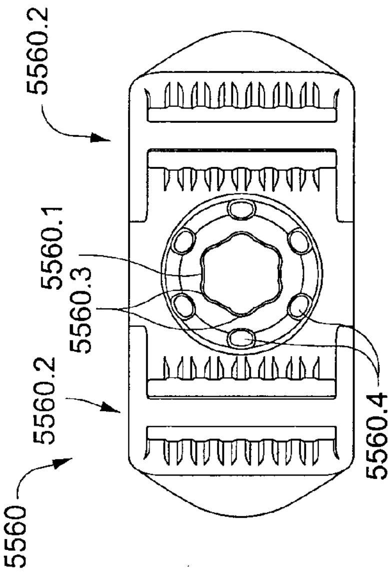


Fig. 5-43-3

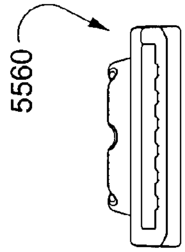


Fig. 5-43-4

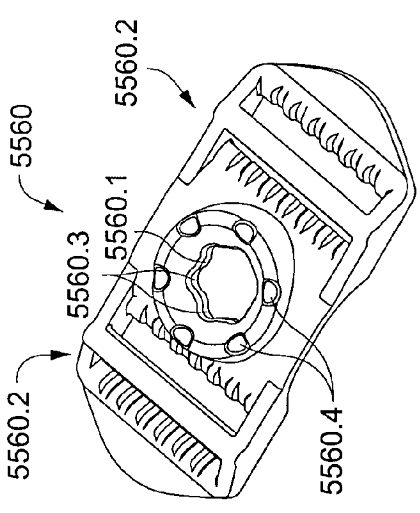


Fig. 5-43-1

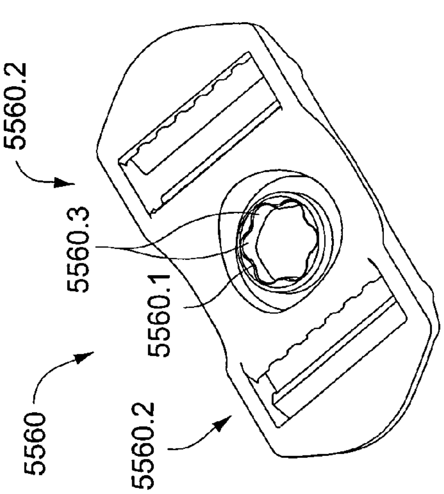


Fig. 5-43-2

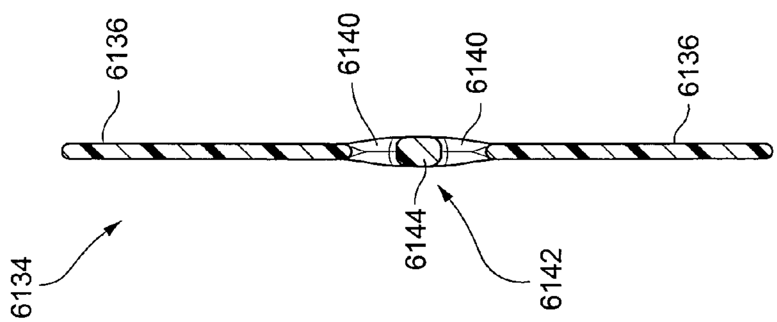


Fig. 5-44-3

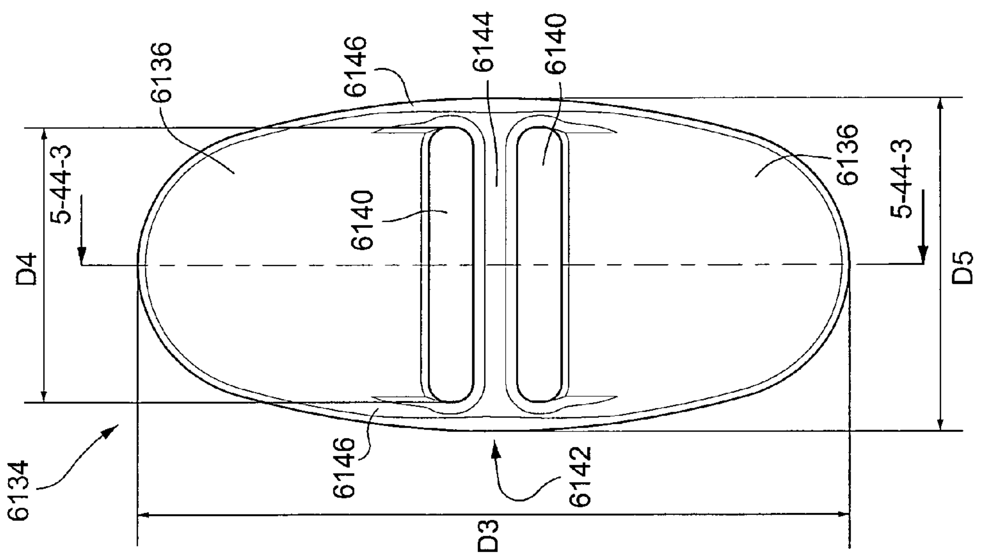


Fig. 5-44-2

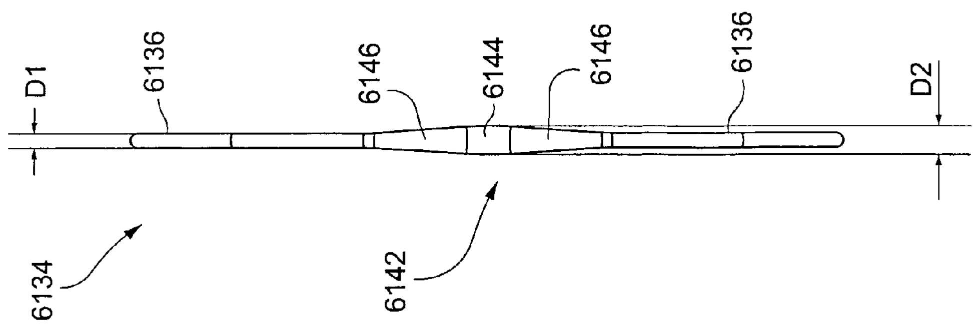


Fig. 5-44-1

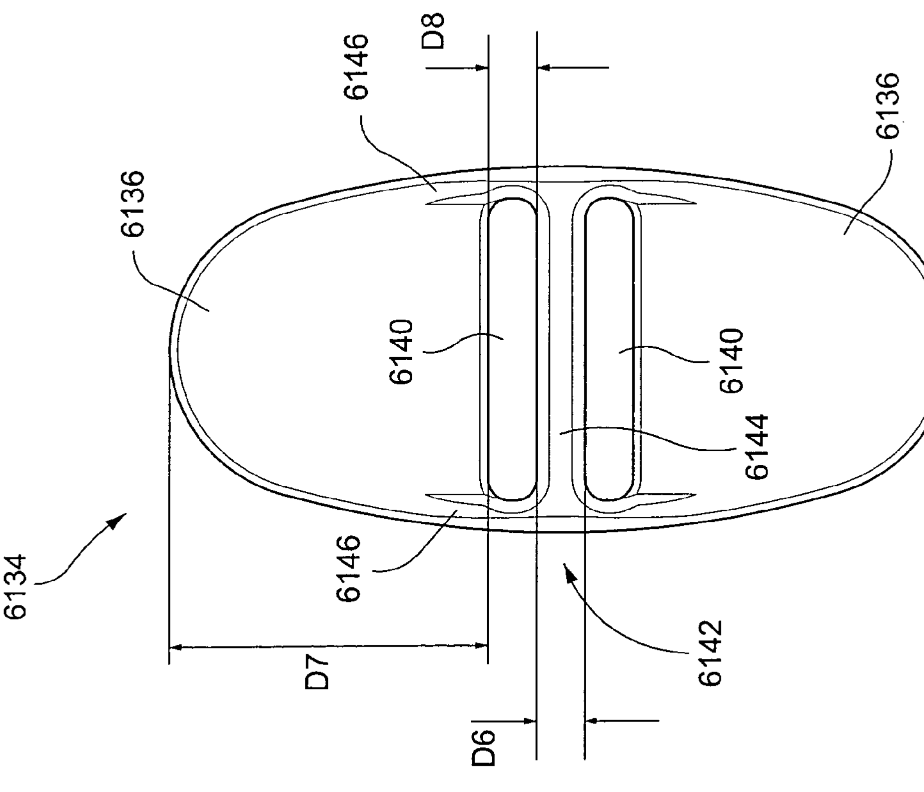


Fig. 5-44-4

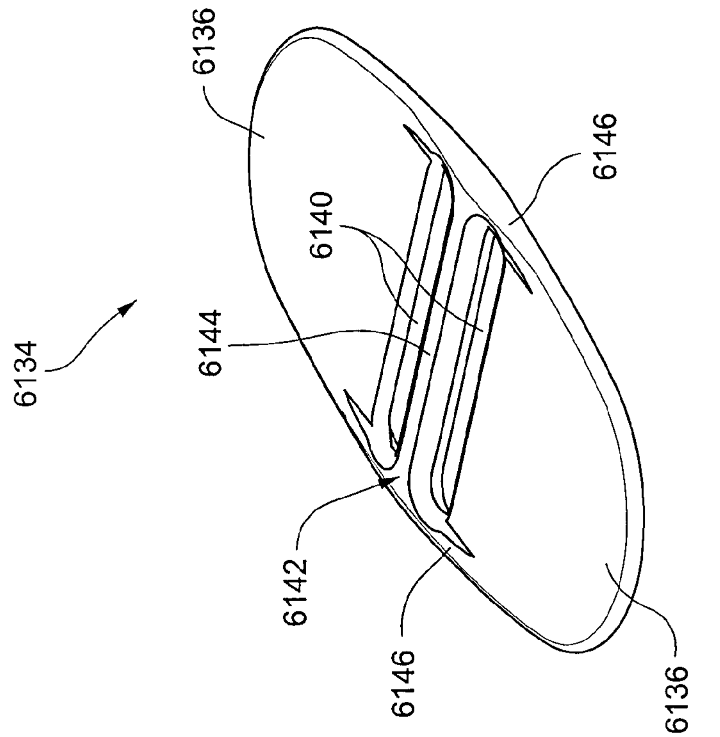


Fig. 5-44-5

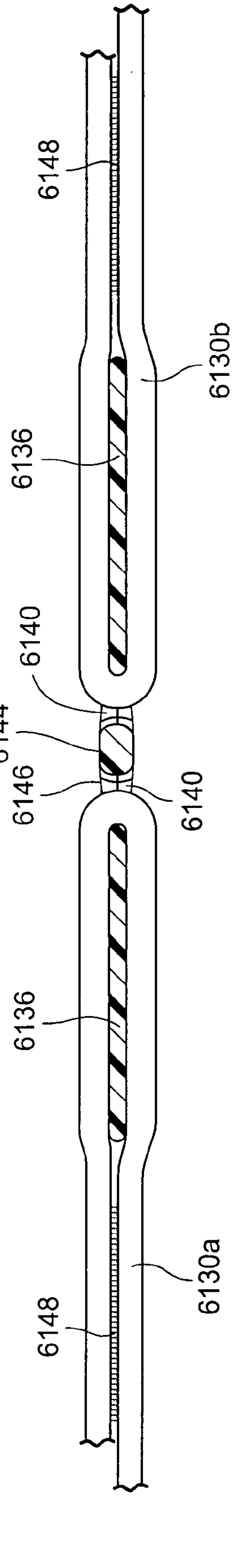


Fig. 5-45

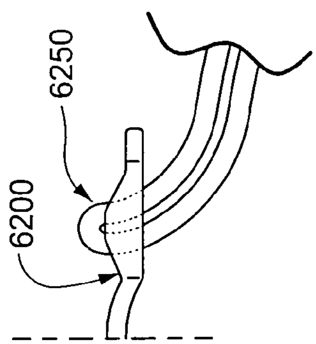


Fig. 5-46
(PRIOR ART)

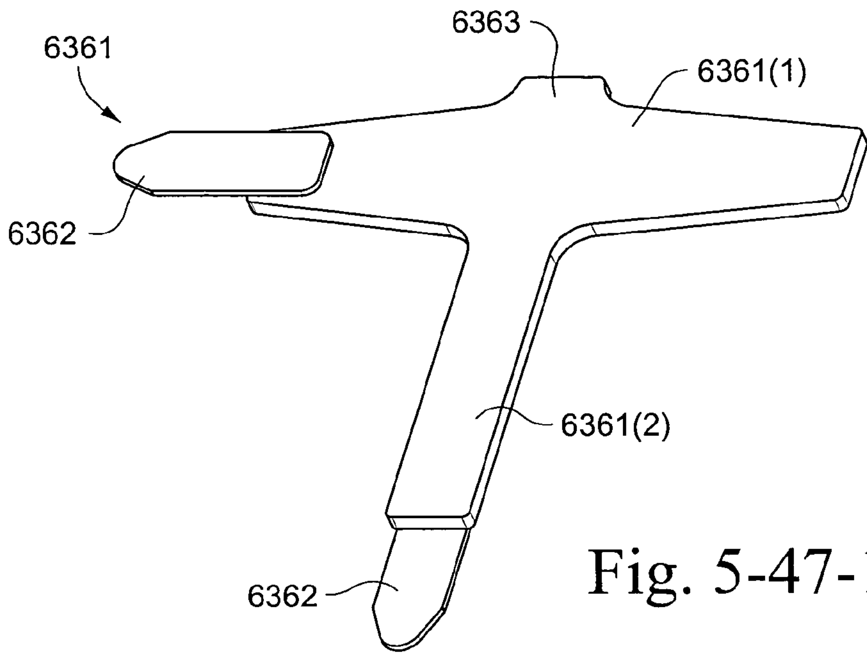


Fig. 5-47-1

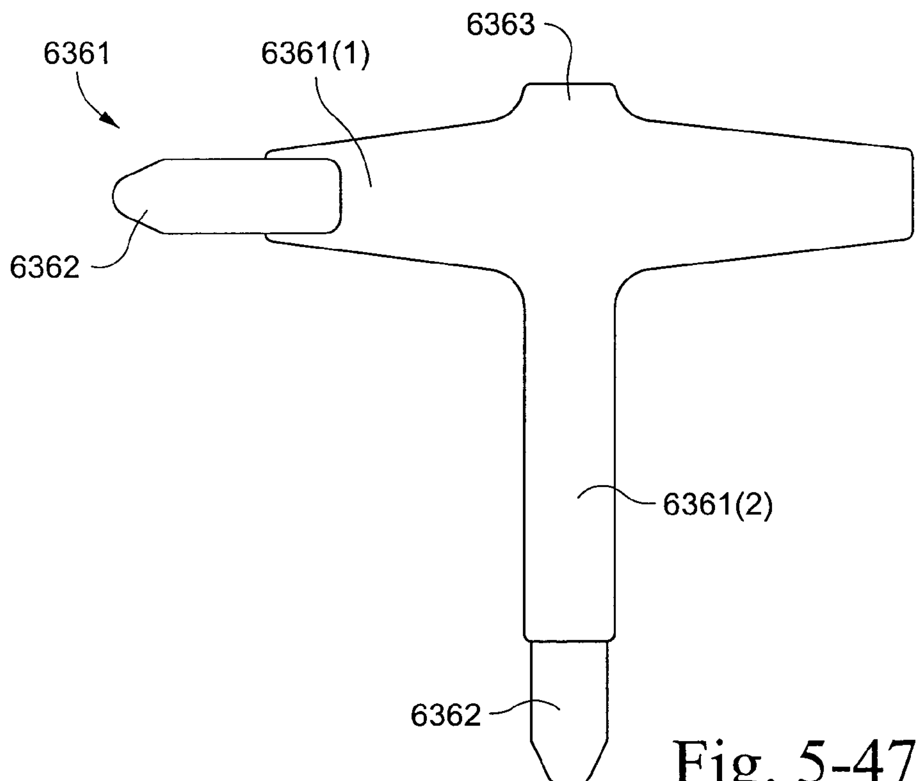


Fig. 5-47-2

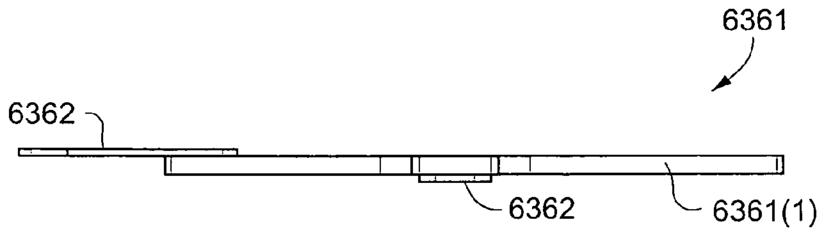
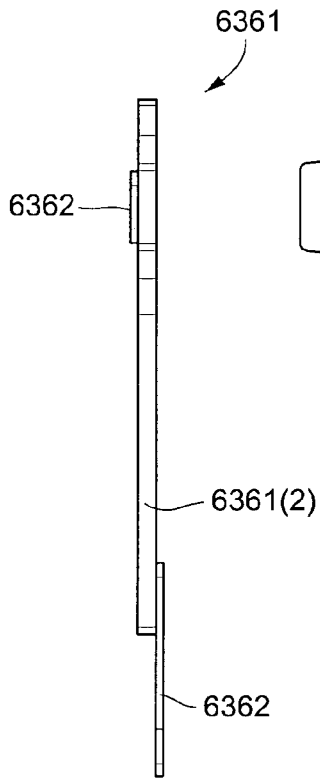


Fig. 5-47-3



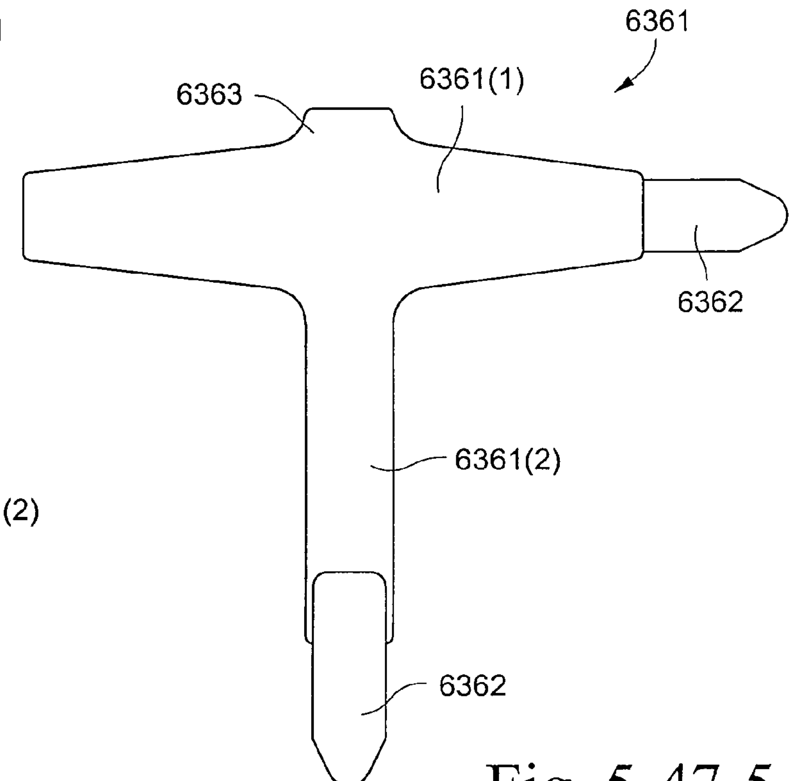


Fig. 5-47-5

Fig. 5-47-4

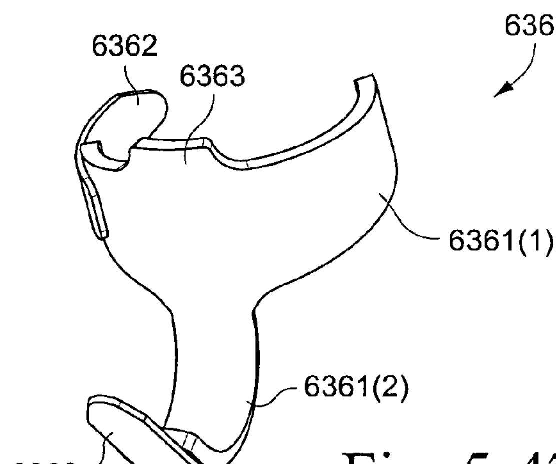


Fig. 5-47-6

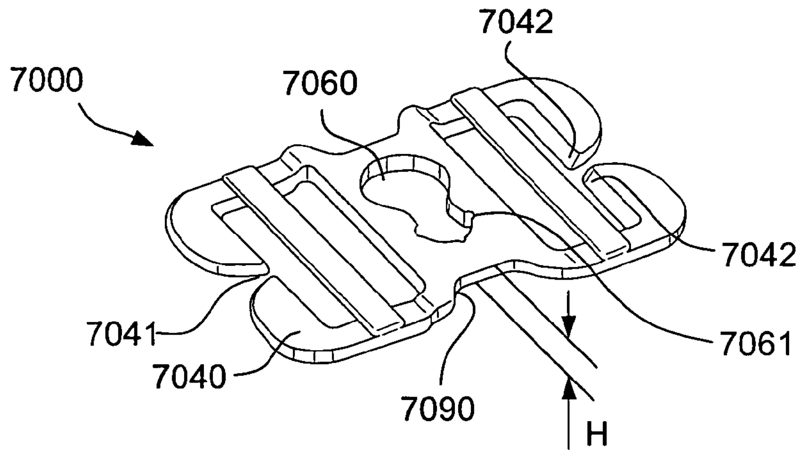


Fig. 5-48

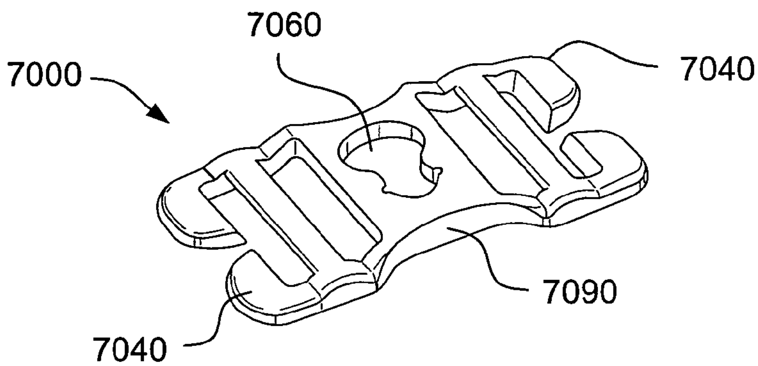


Fig. 5-49

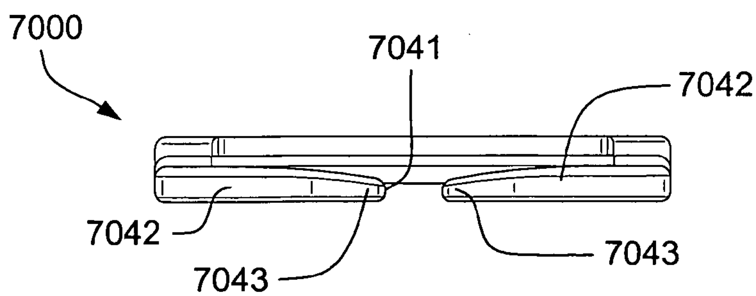


Fig. 5-50

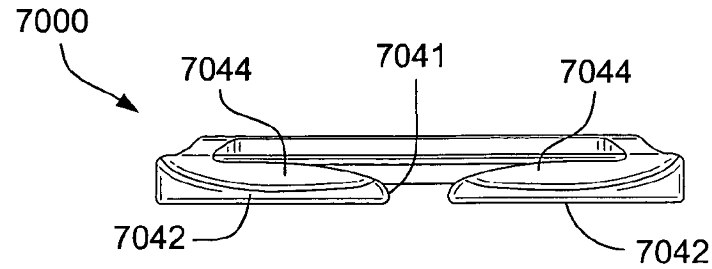


Fig. 5-51

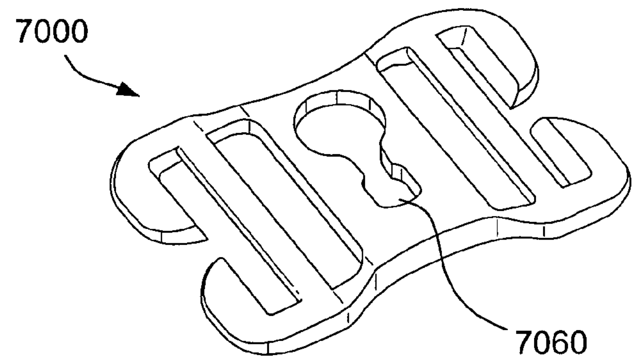


Fig. 5-52

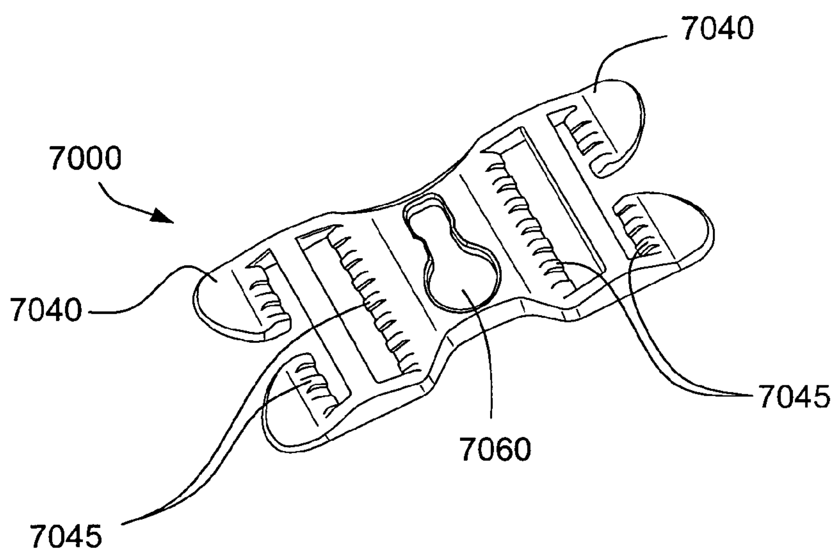


Fig. 5-53

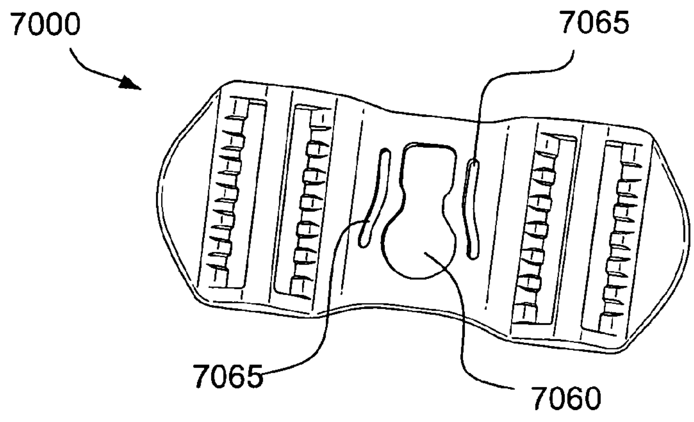


Fig. 5-54

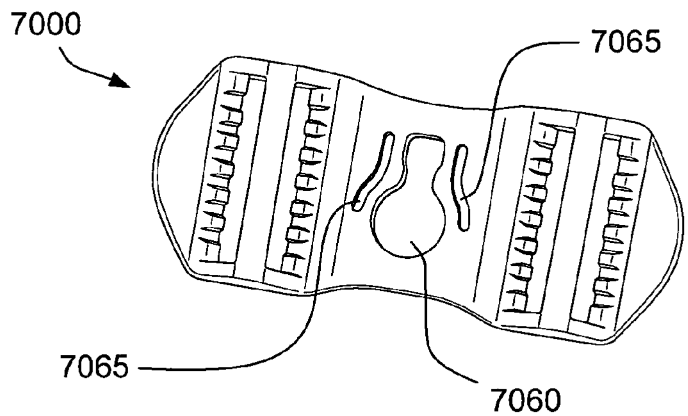


Fig. 5-55

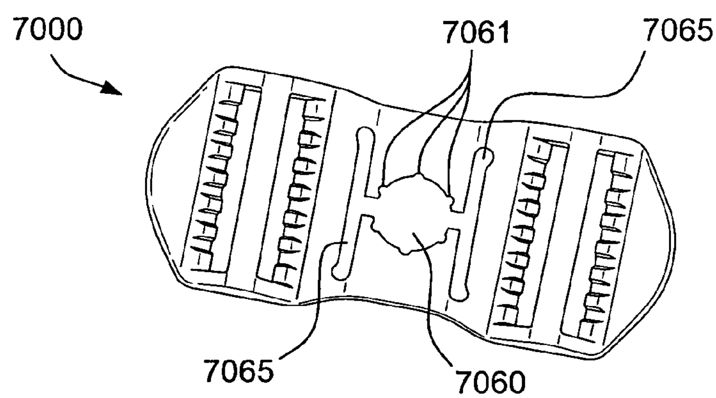


Fig. 5-56

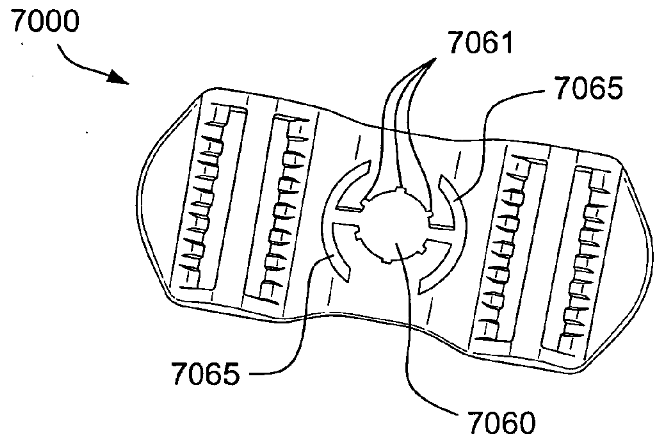


Fig. 5-57

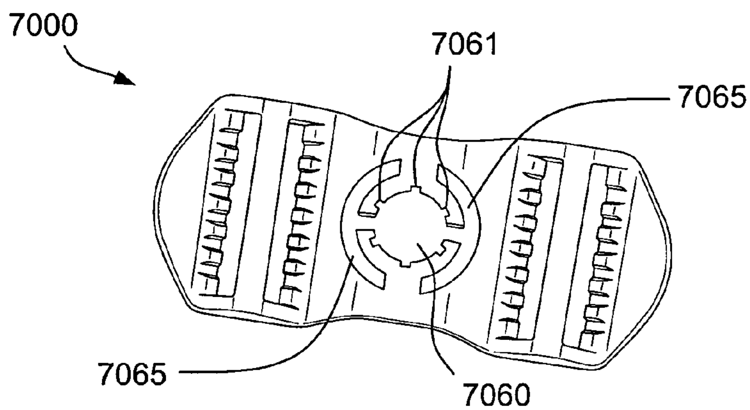


Fig. 5-58

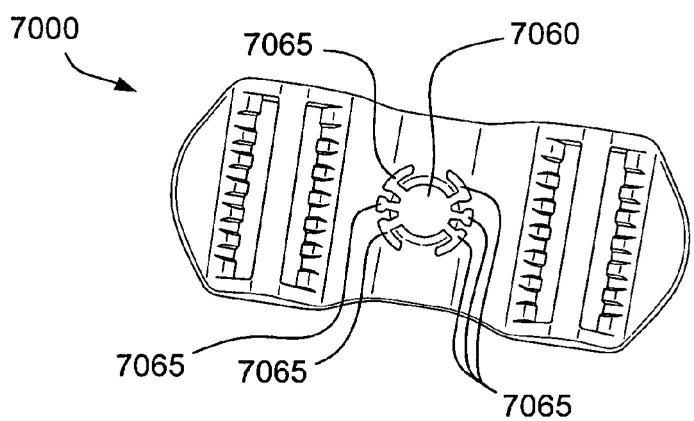


Fig. 5-59

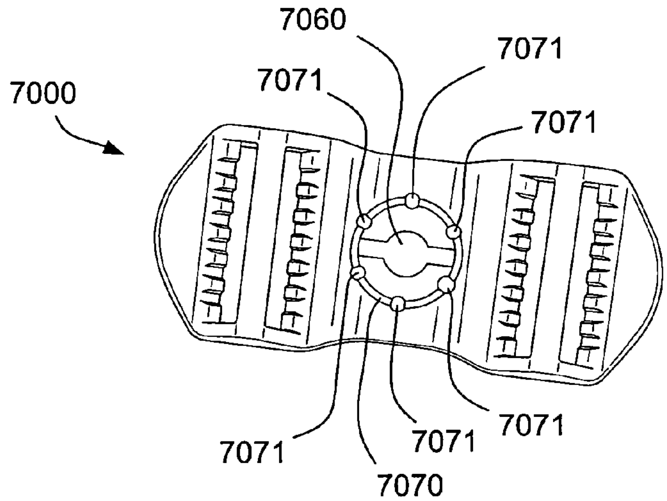


Fig. 5-60

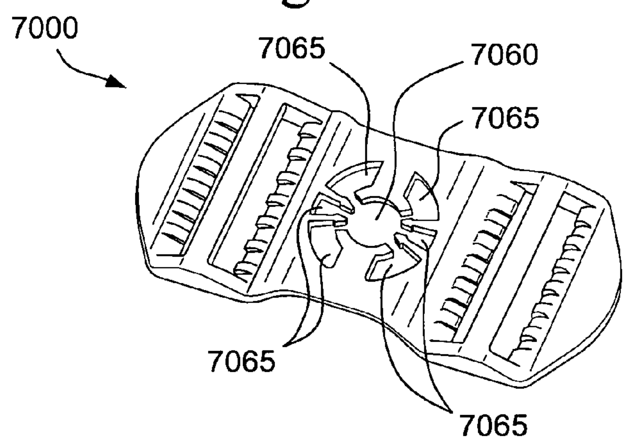


Fig. 5-61

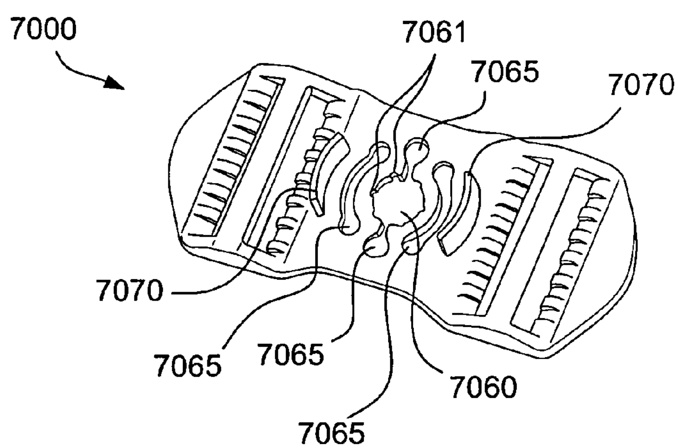


Fig. 5-62

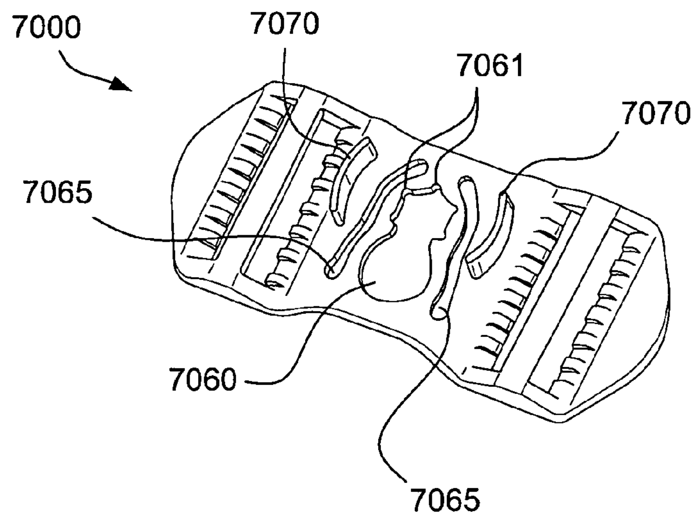


Fig. 5-63

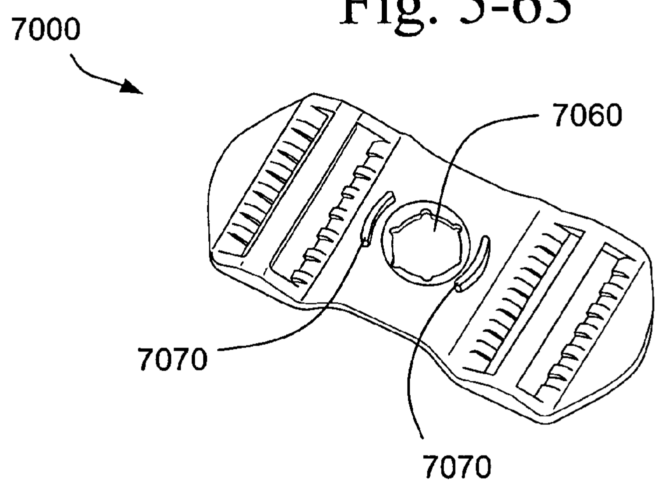


Fig. 5-64

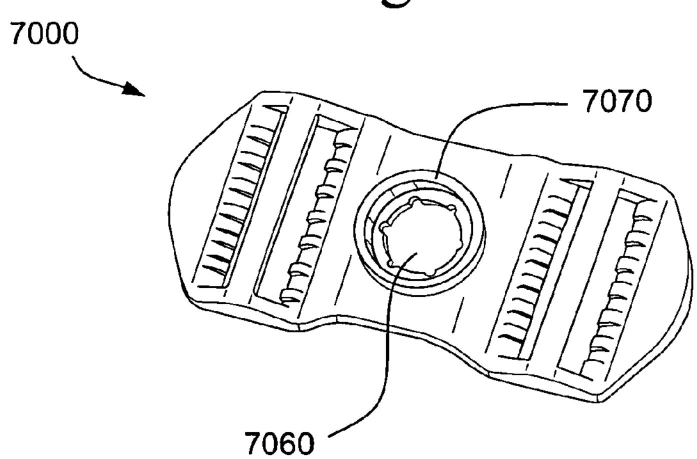


Fig. 5-65

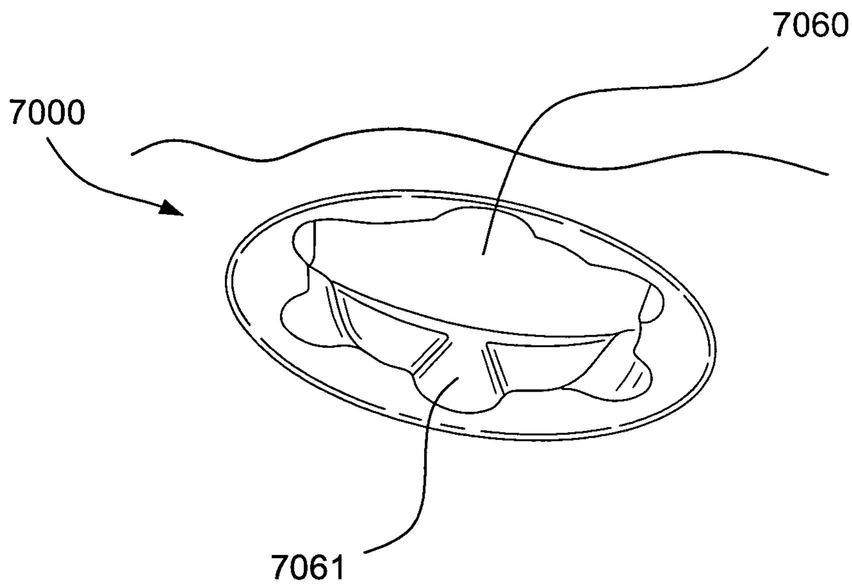


Fig. 5-66

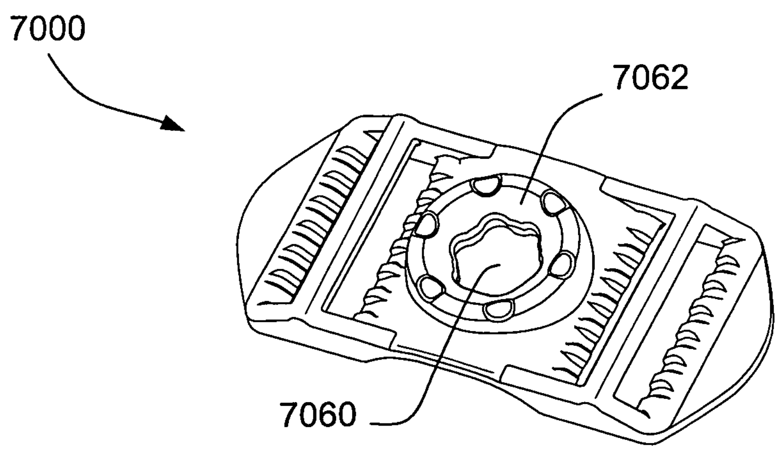


Fig. 5-67

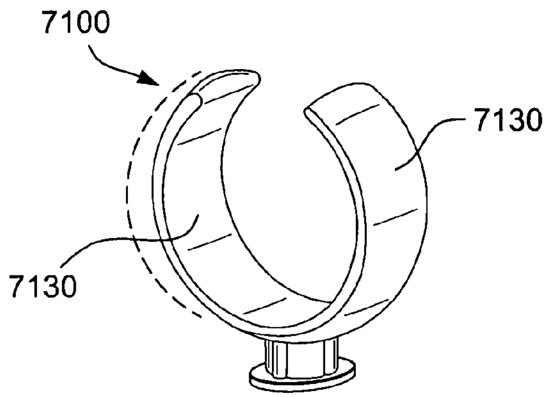


Fig. 5-68

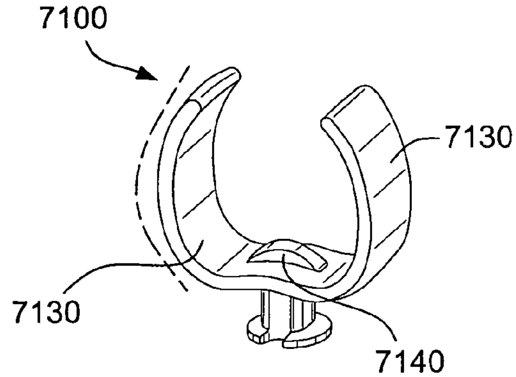


Fig. 5-69

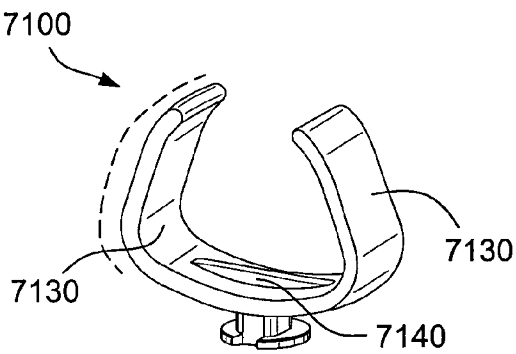


Fig. 5-70

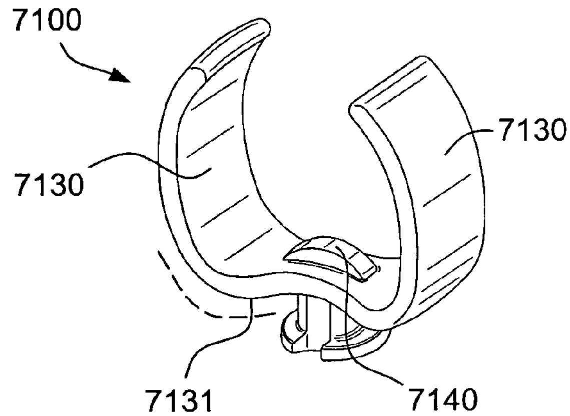


Fig. 5-71

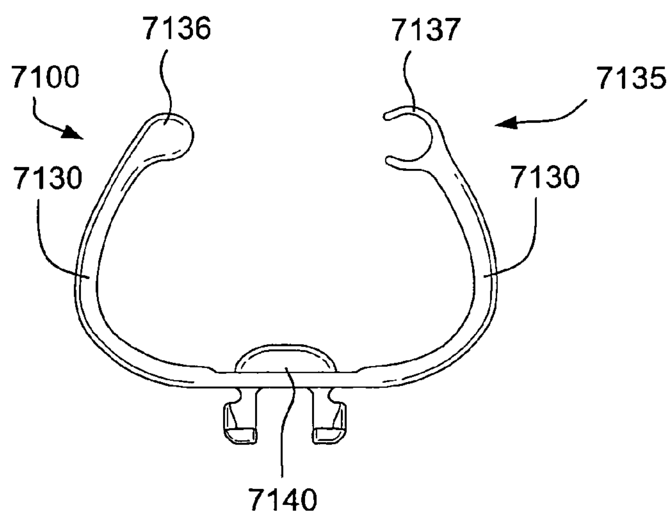


Fig. 5-72

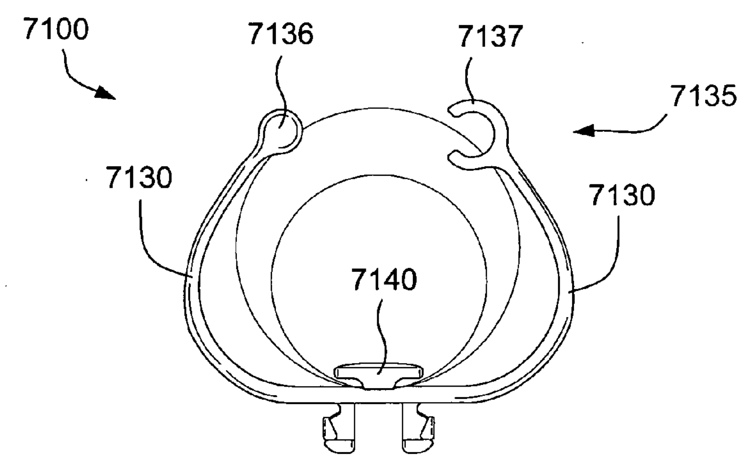


Fig. 5-73

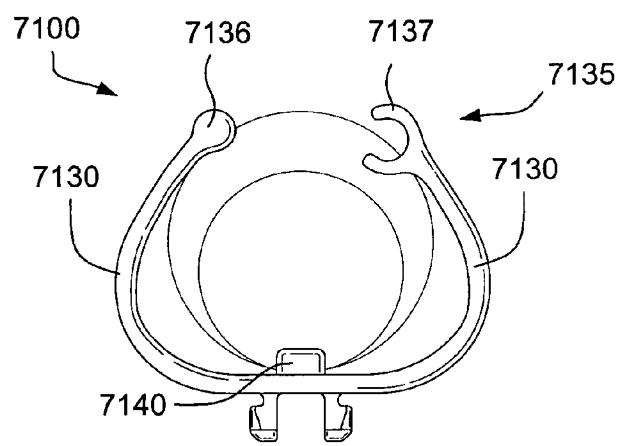


Fig. 5-74

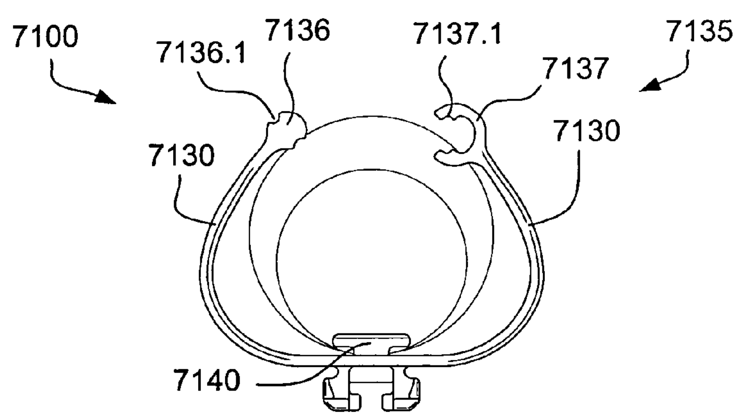


Fig. 5-75

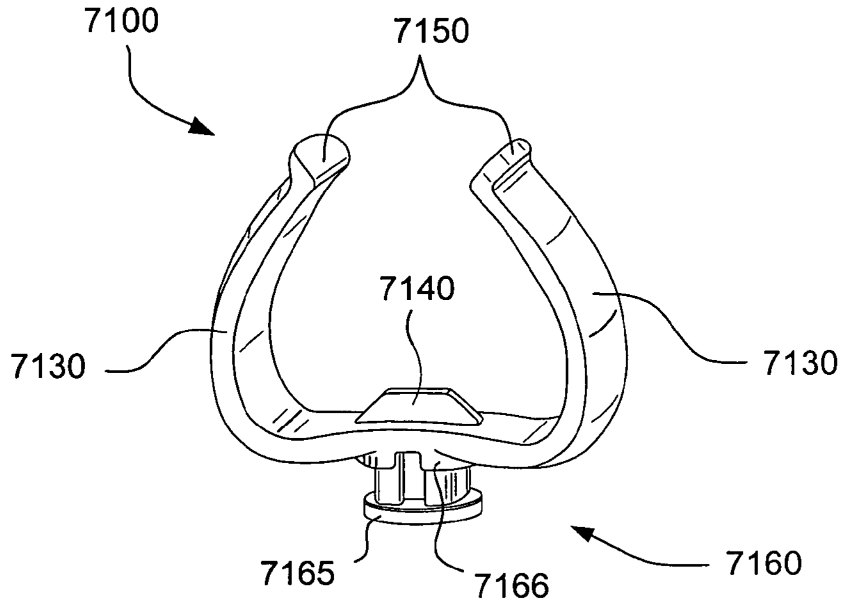


Fig. 5-76

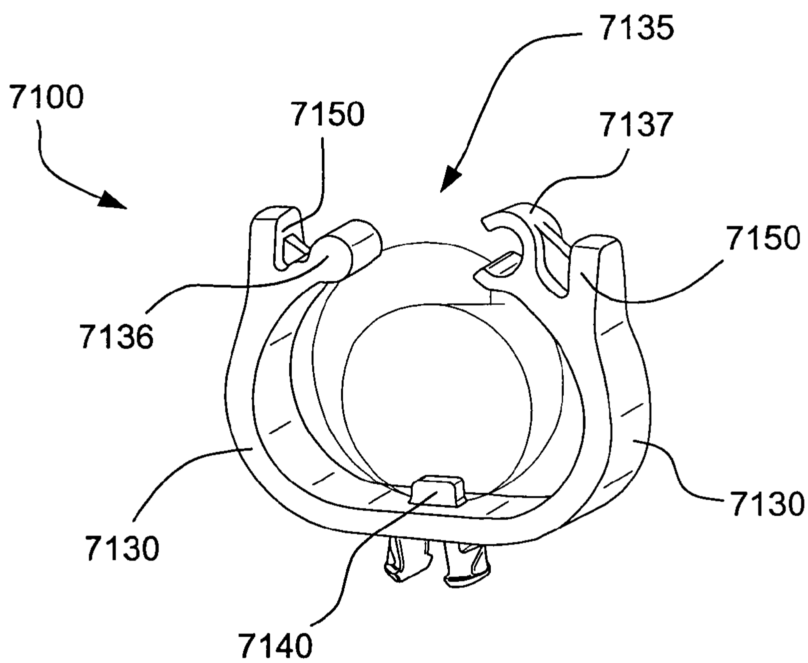


Fig. 5-77

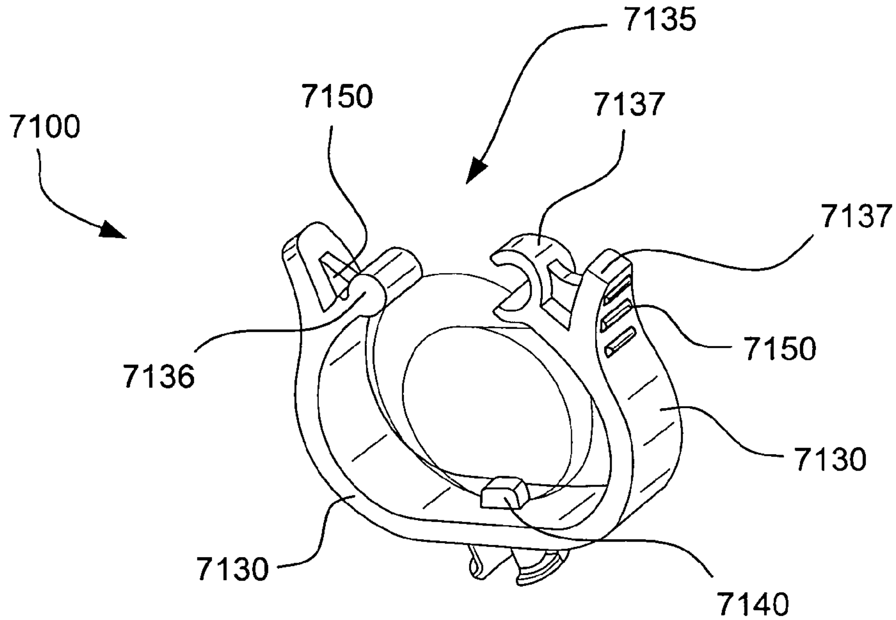


Fig. 5-78

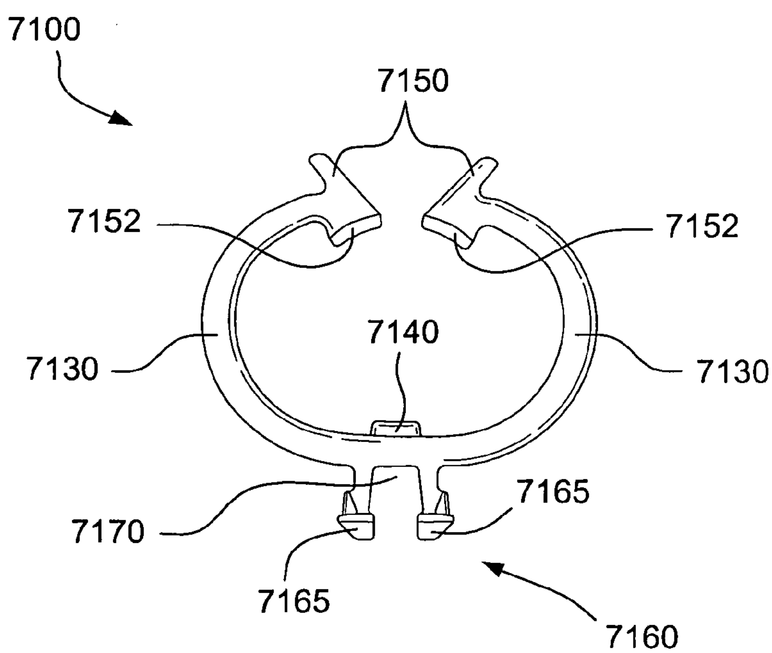


Fig. 5-79

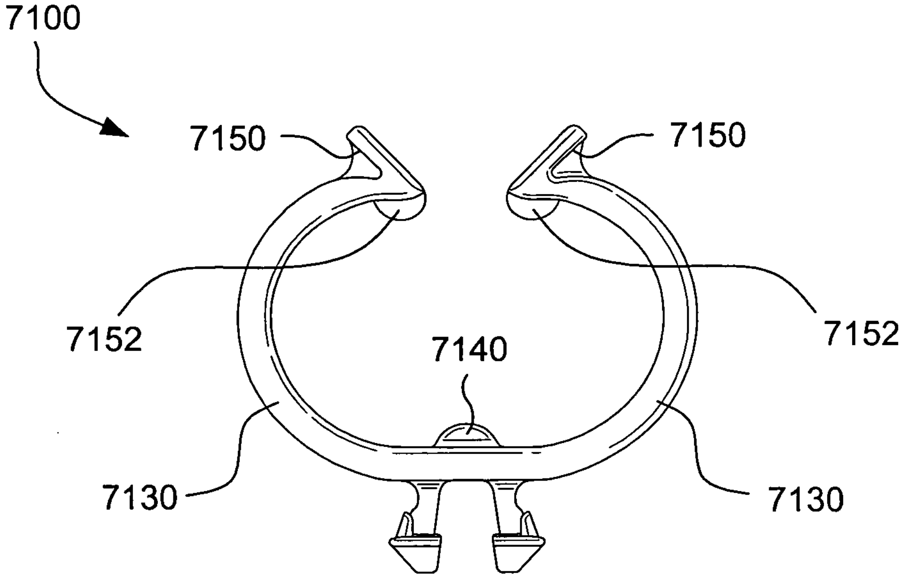


Fig. 5-80

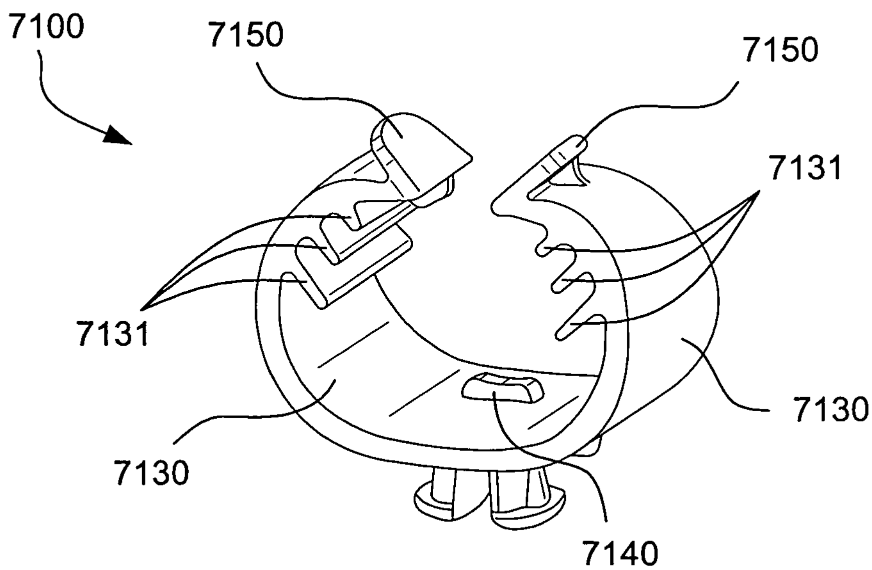


Fig. 5-81

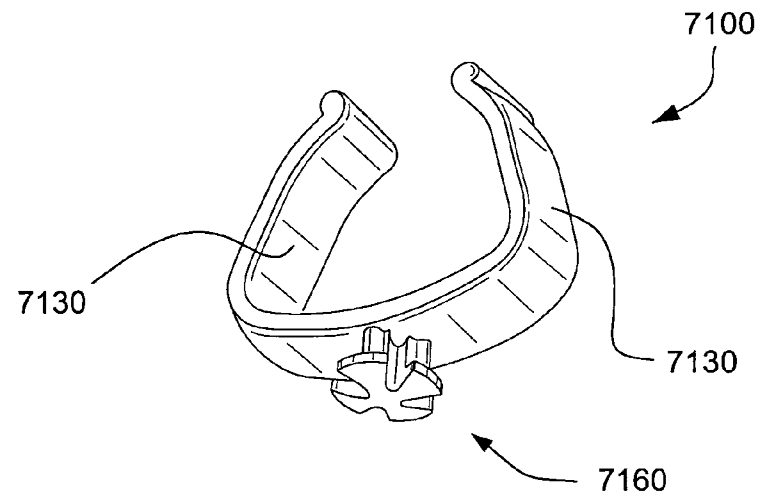


Fig. 5-82

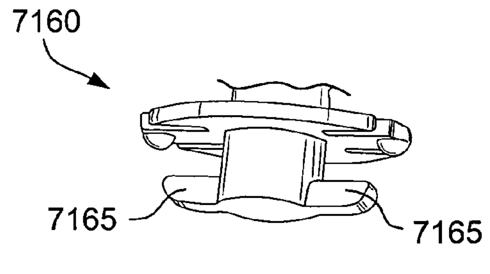


Fig. 5-83

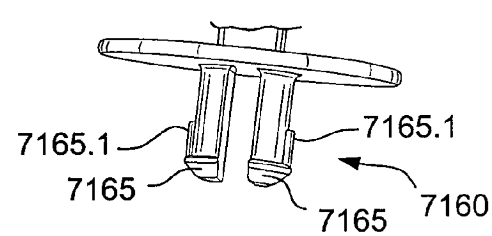


Fig. 5-84

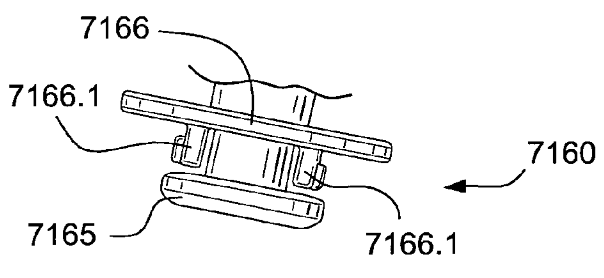


Fig. 5-85

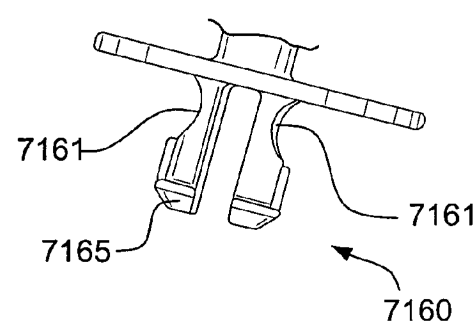


Fig. 5-86

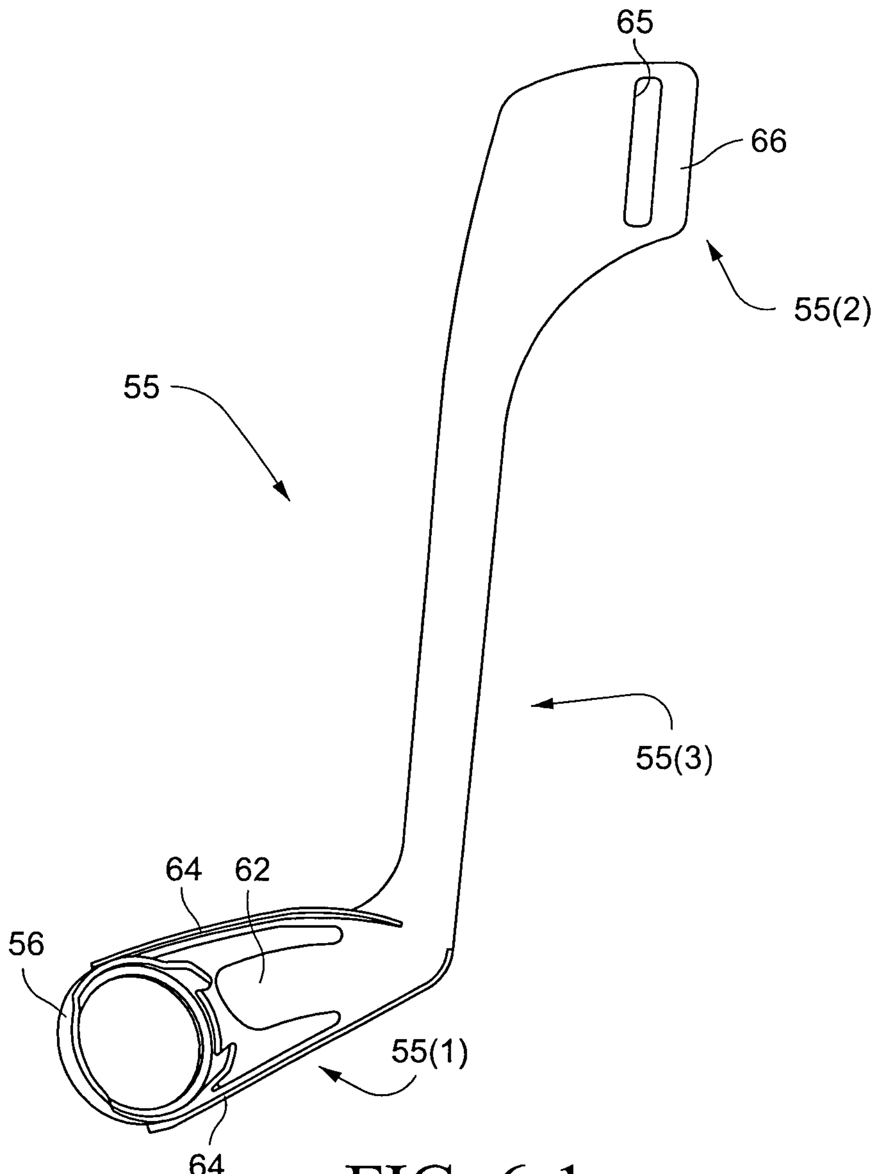


FIG. 6-1

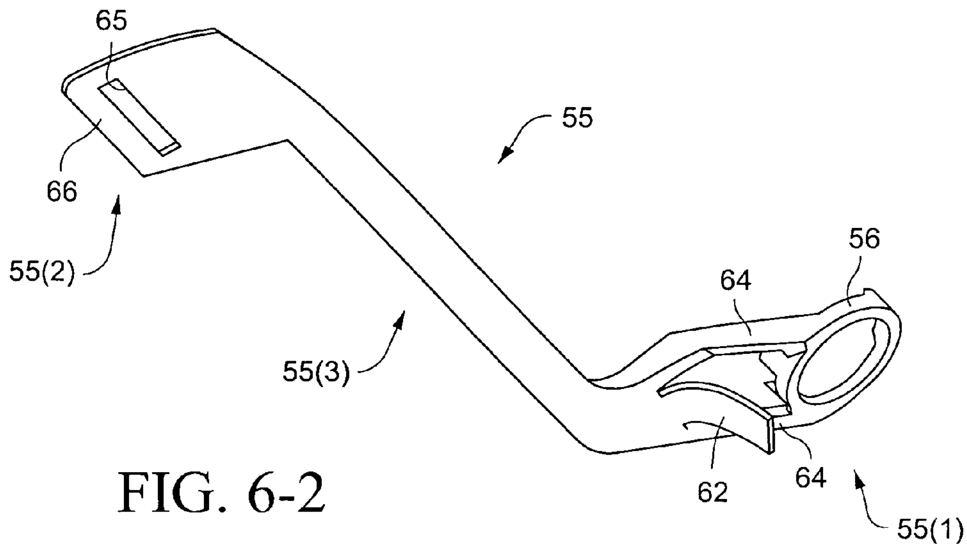


FIG. 6-2

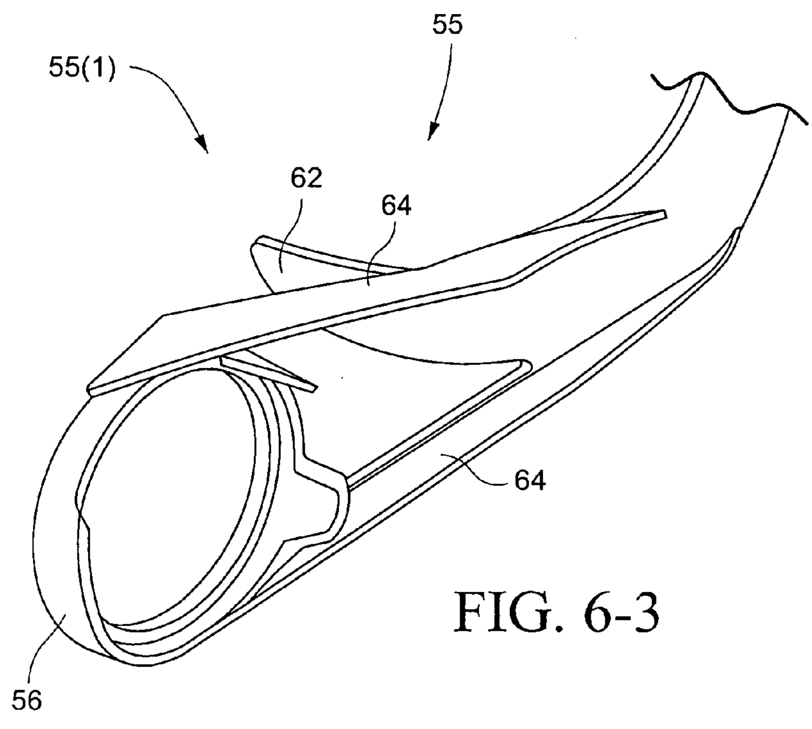


FIG. 6-3

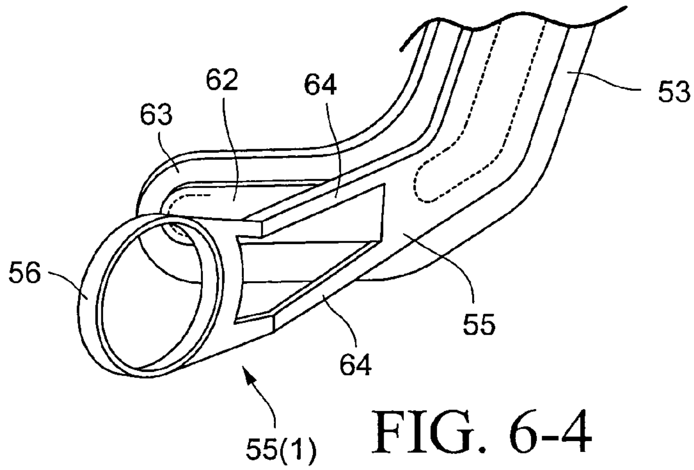


FIG. 6-4

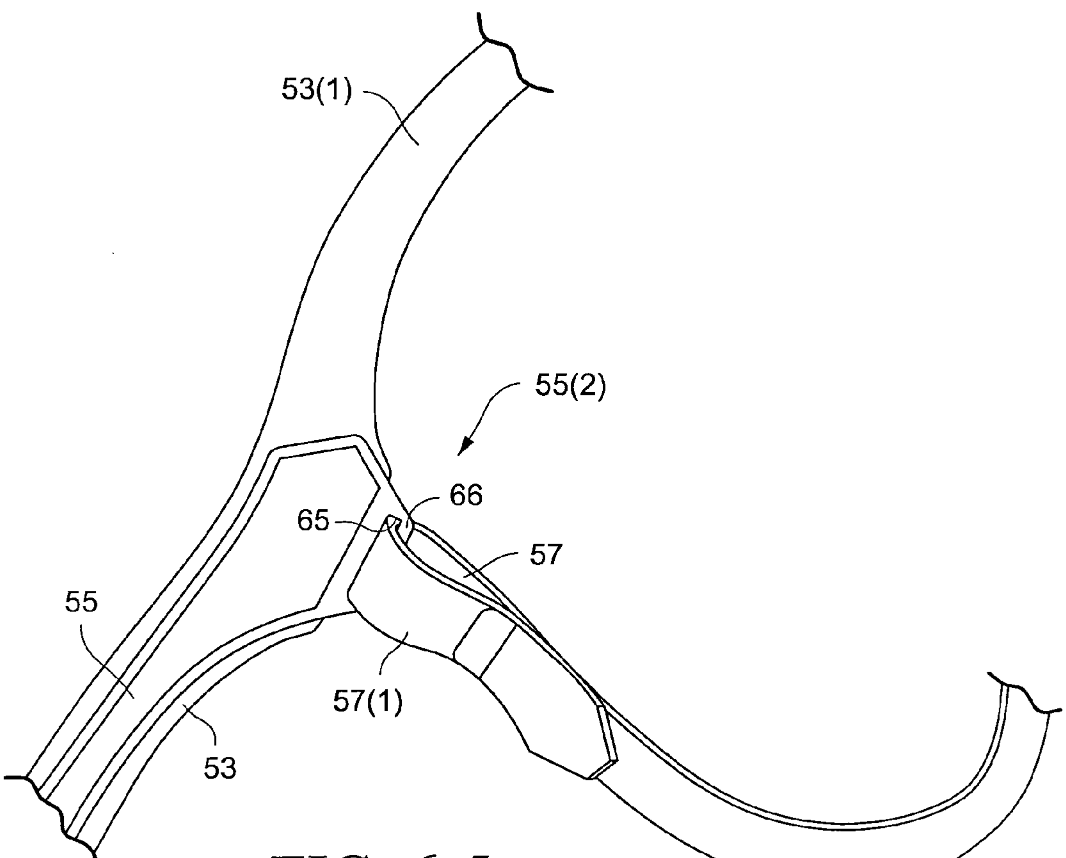


FIG. 6-5

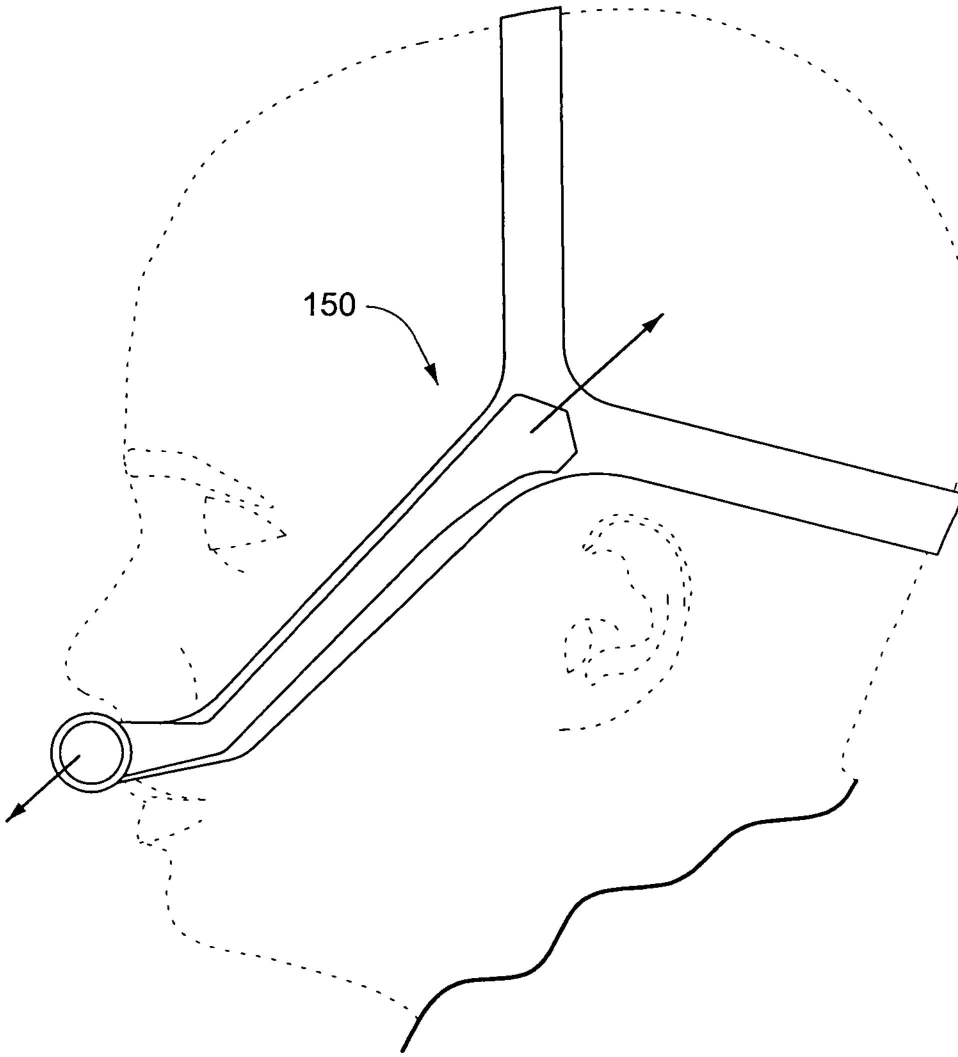


FIG. 7-1
(Prior Art)

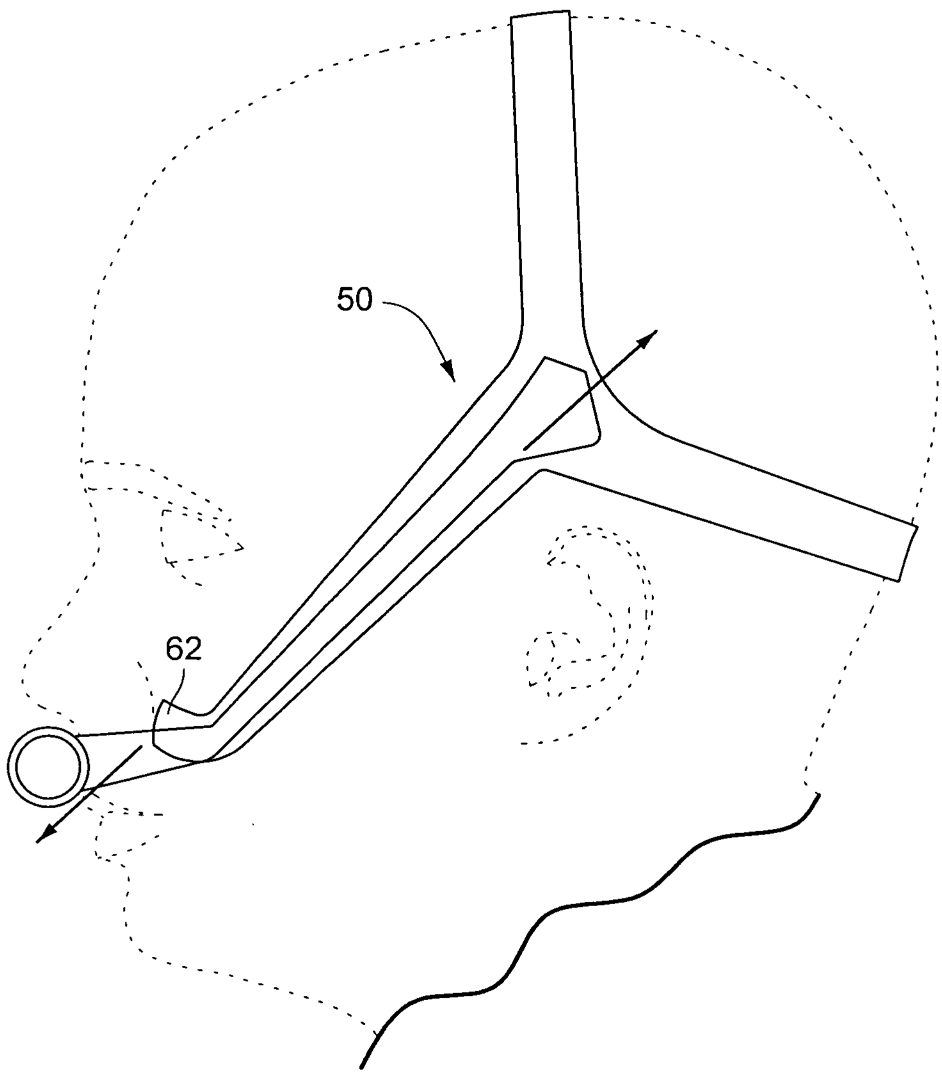


FIG. 7-2

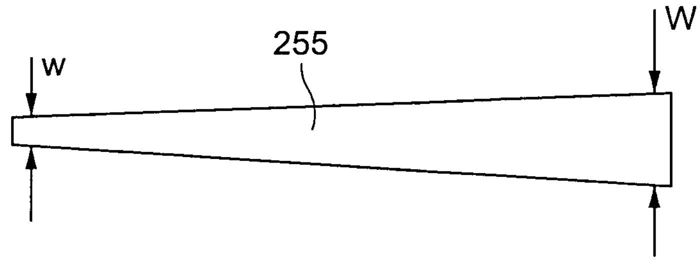


FIG. 8-1

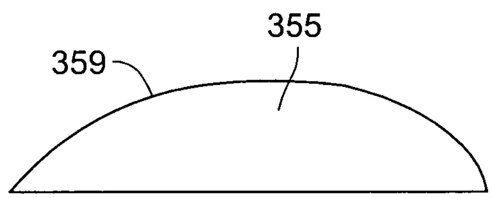


FIG. 8-2

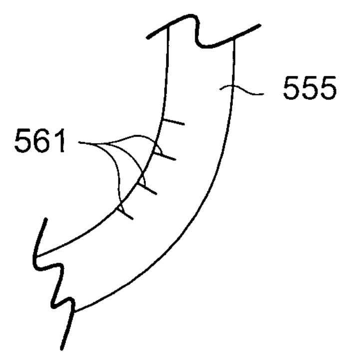


FIG. 8-4

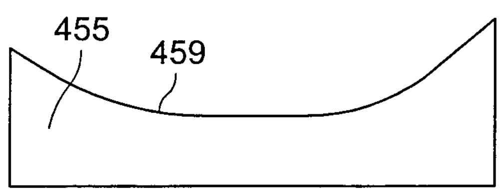


FIG. 8-3

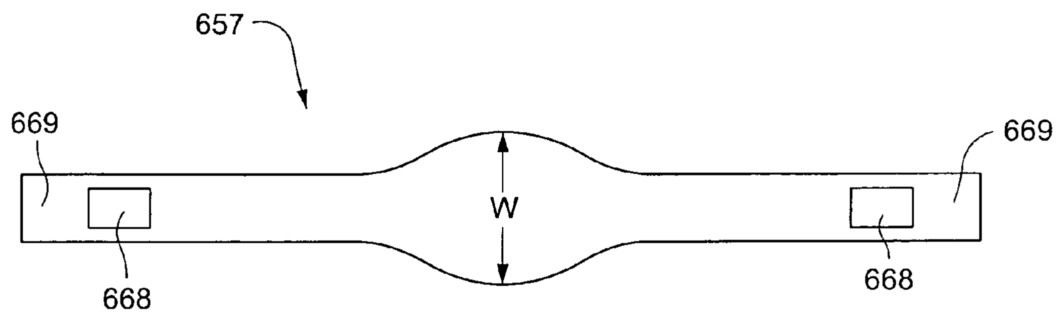


FIG. 9

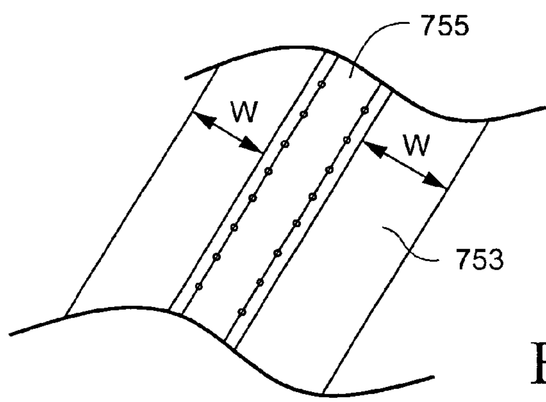


FIG. 10-1

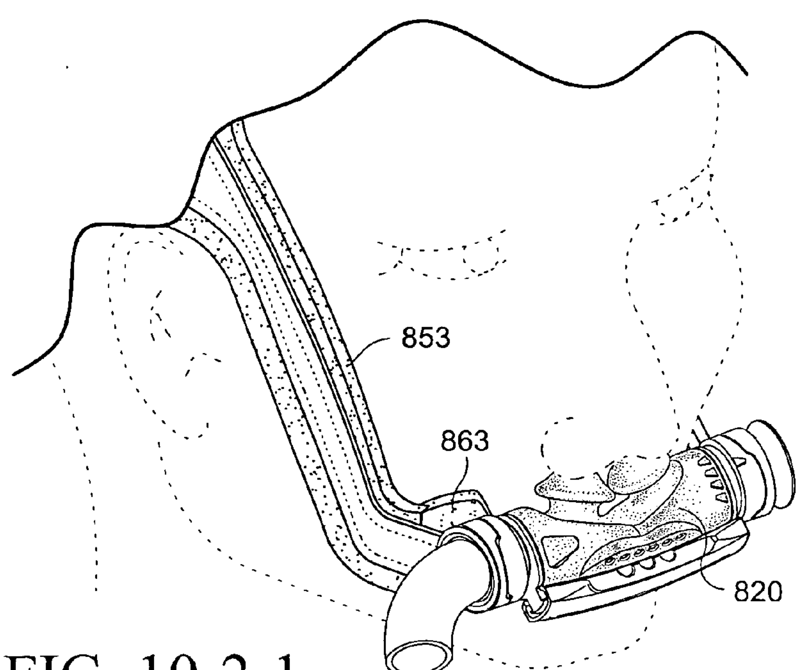


FIG. 10-2-1

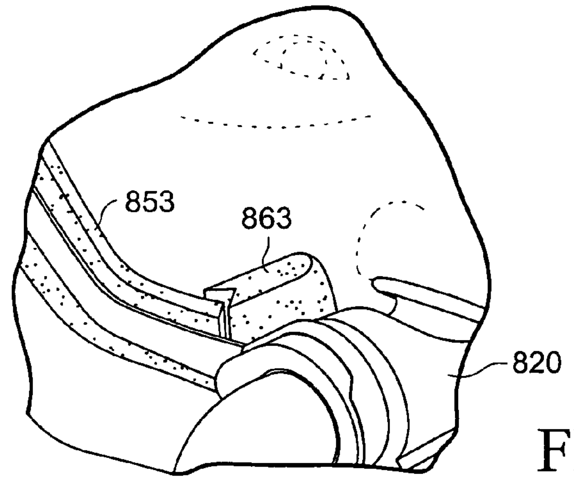


FIG. 10-2-2

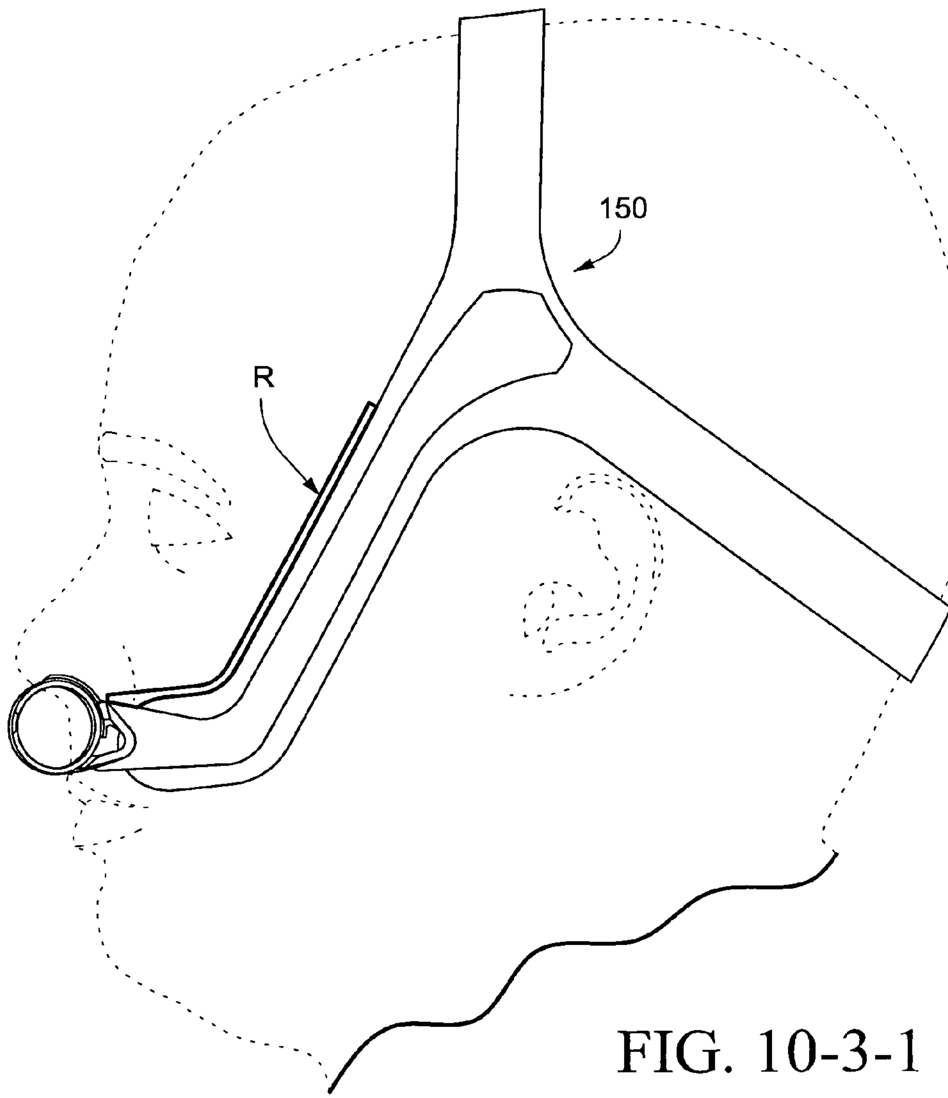


FIG. 10-3-1
(Prior Art)

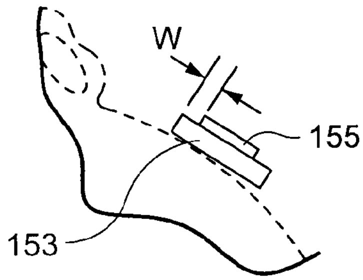


FIG. 10-3-2
(Prior Art)

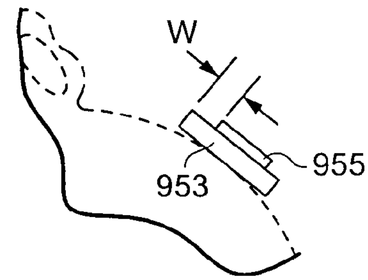


FIG. 10-4

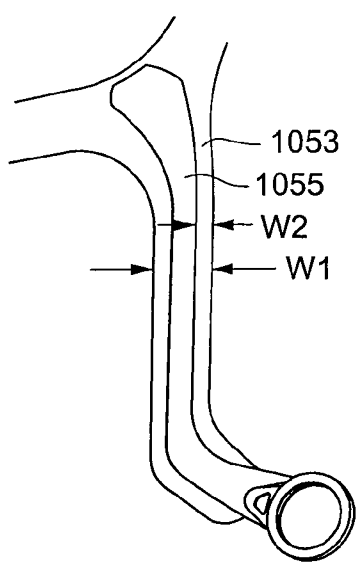


FIG. 10-5

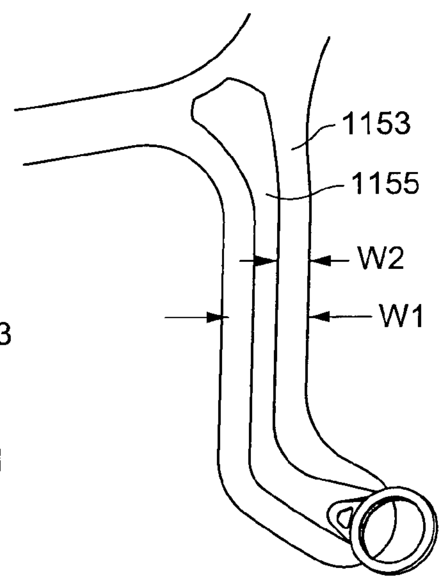


FIG. 10-6

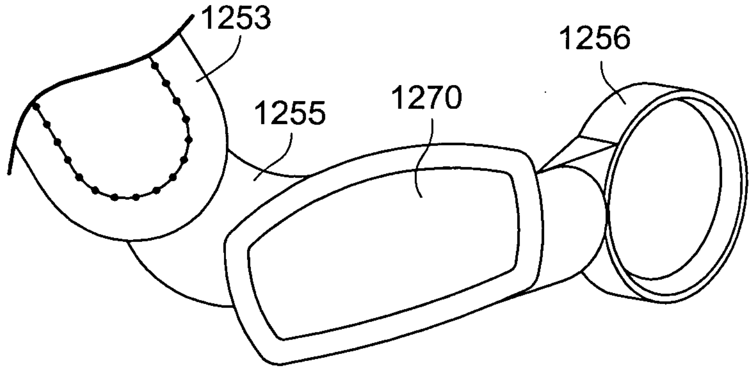


FIG. 10-7-1

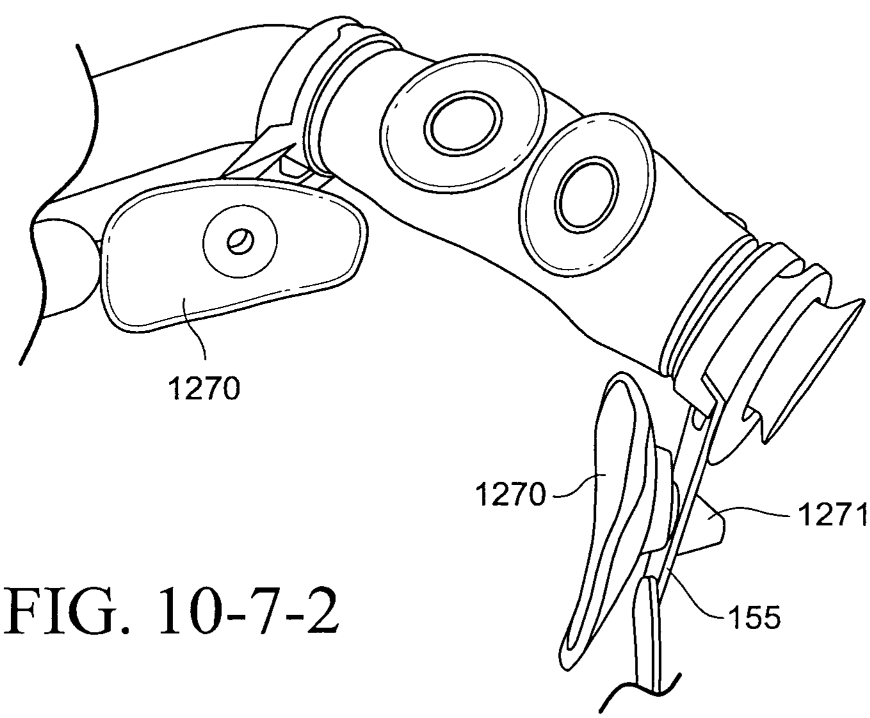


FIG. 10-7-2

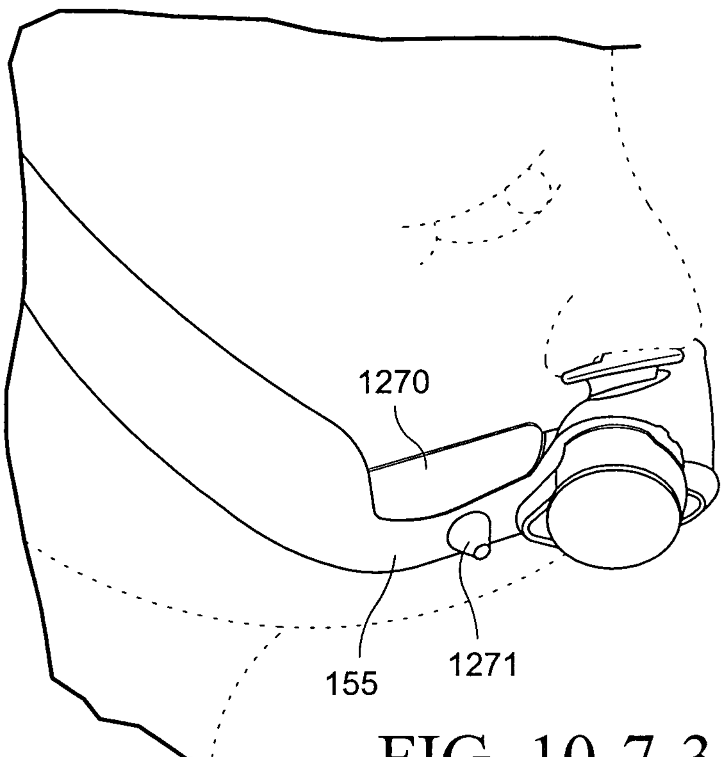


FIG. 10-7-3

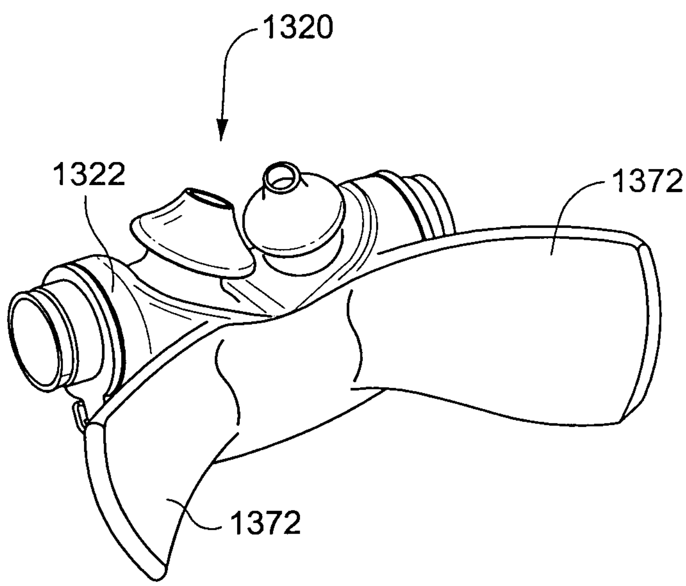


FIG. 10-8-1

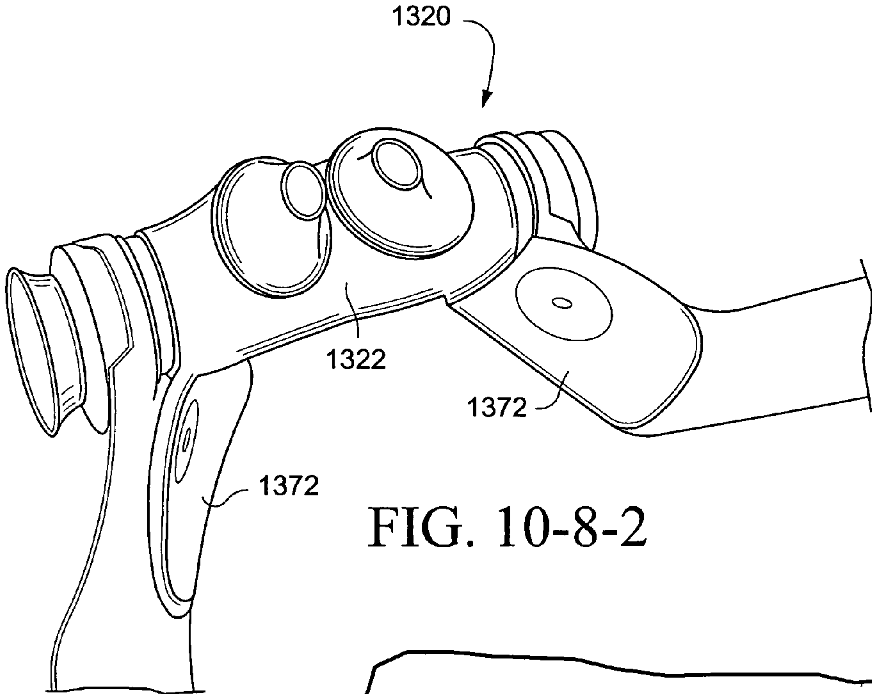


FIG. 10-8-2

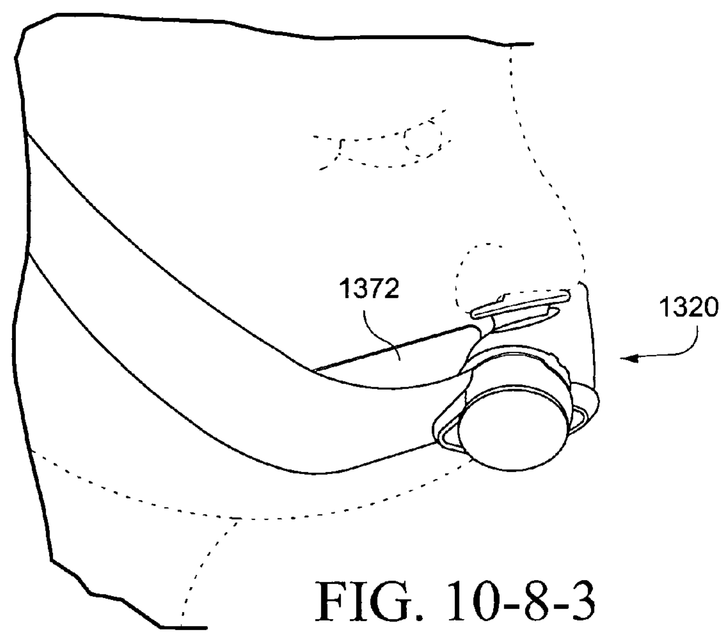


FIG. 10-8-3

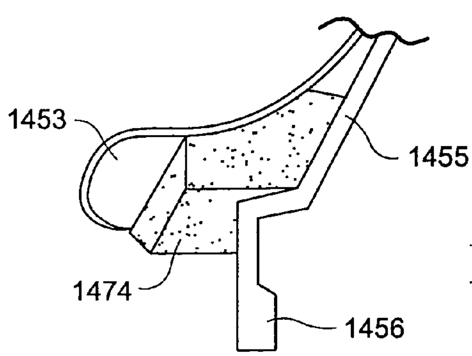


FIG. 10-9-1

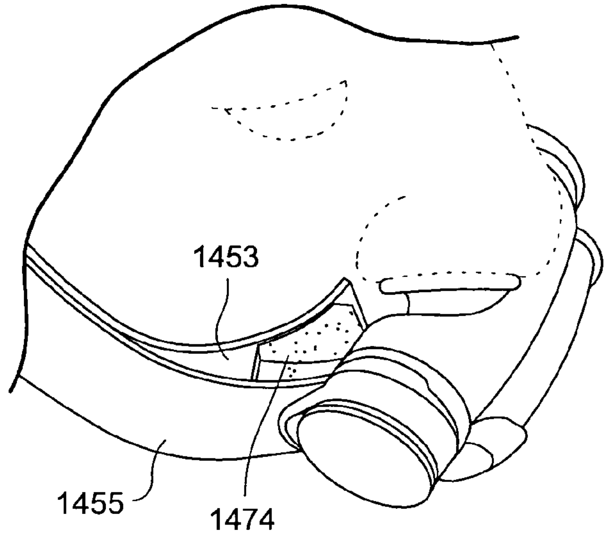


FIG. 10-9-2

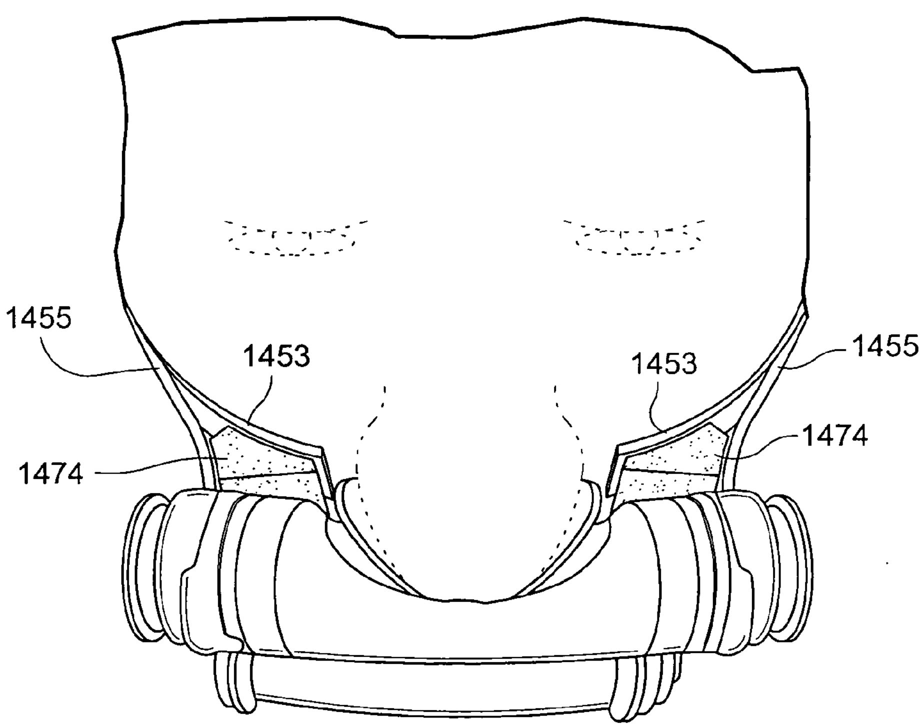


FIG. 10-9-3

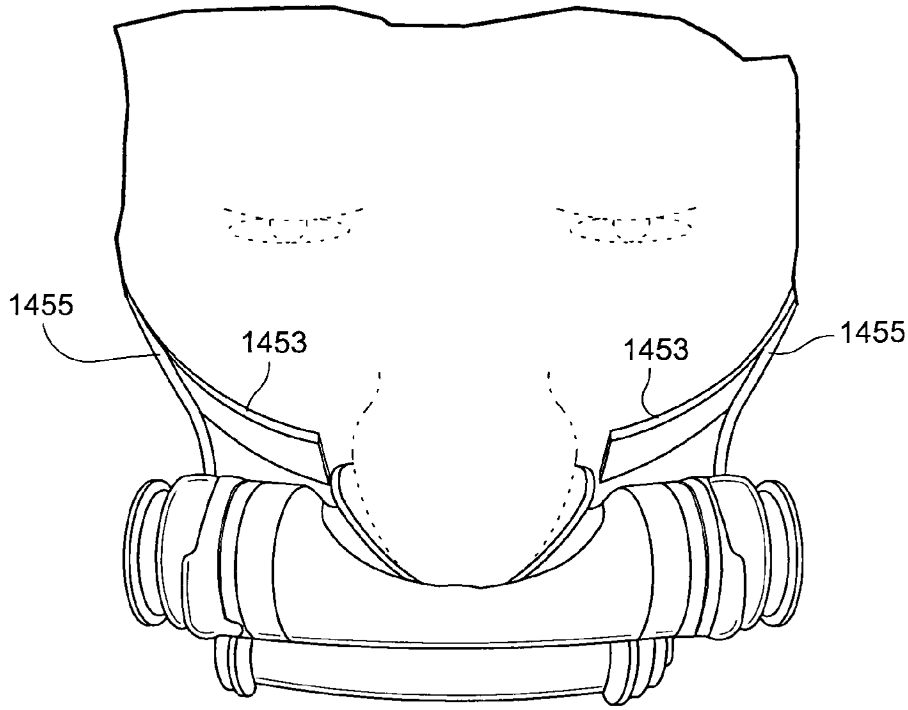


FIG. 10-9-4

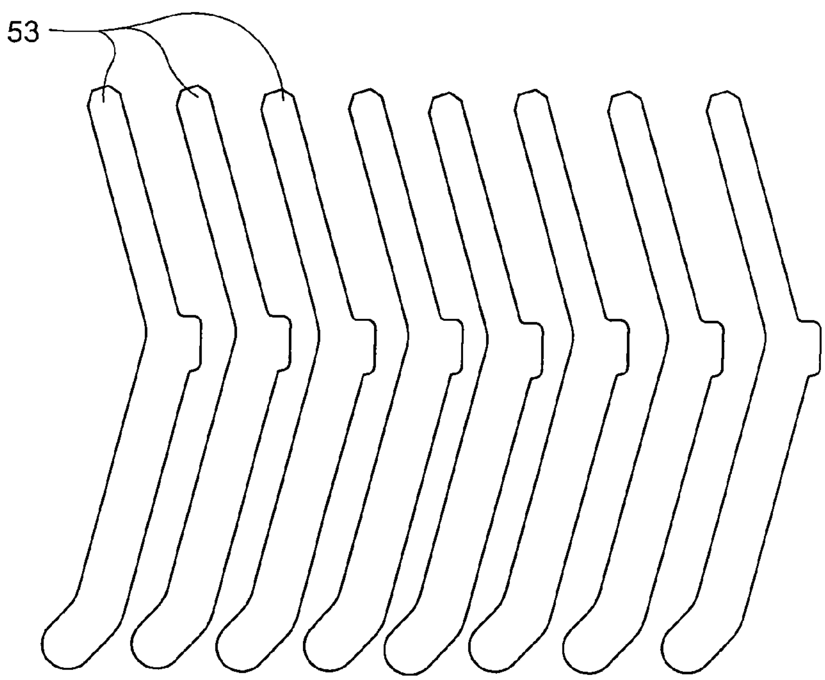


FIG. 11-1

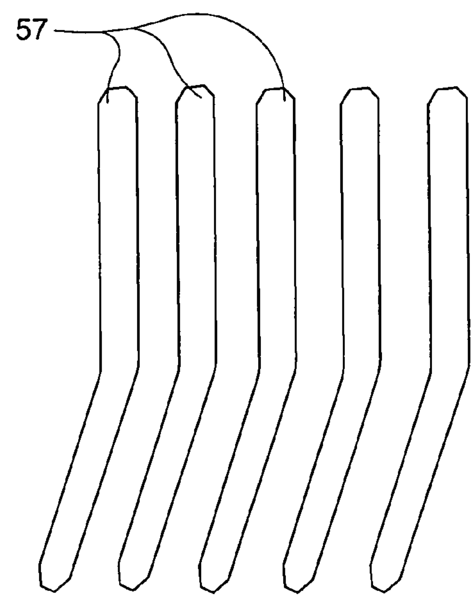


FIG. 11-2

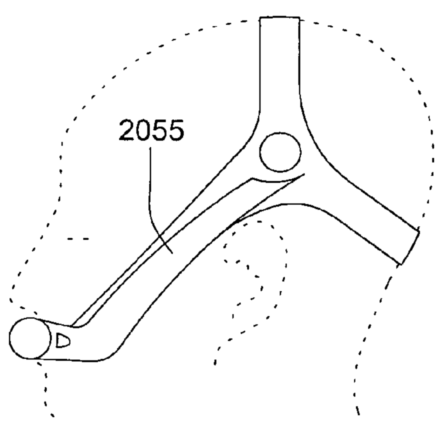


FIG. 12-1

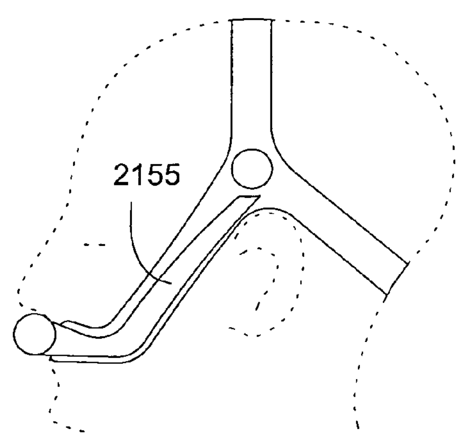


FIG. 12-2

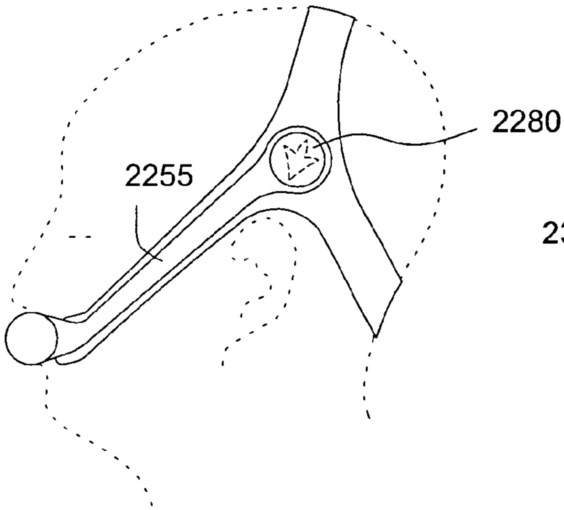


FIG. 12-3

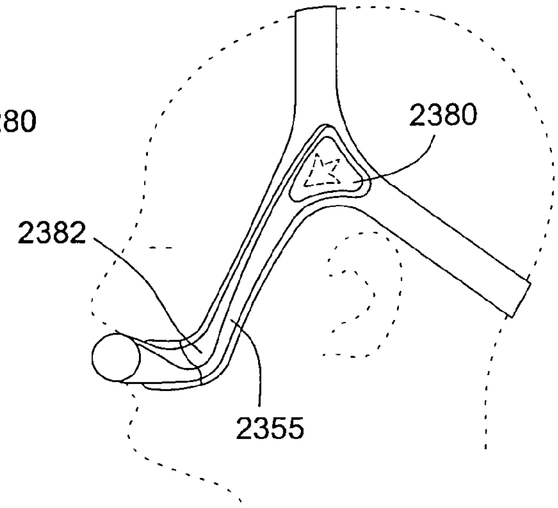


FIG. 12-4

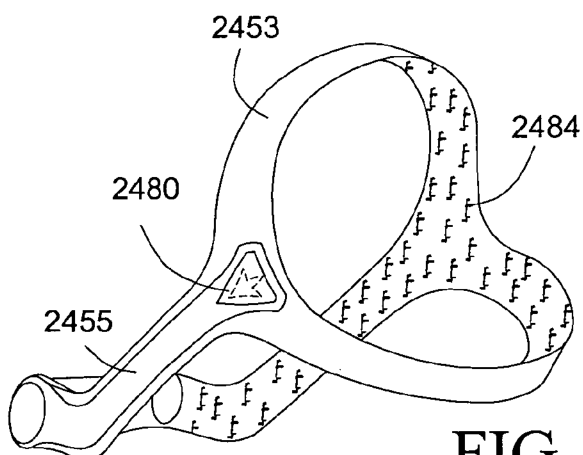


FIG. 12-5

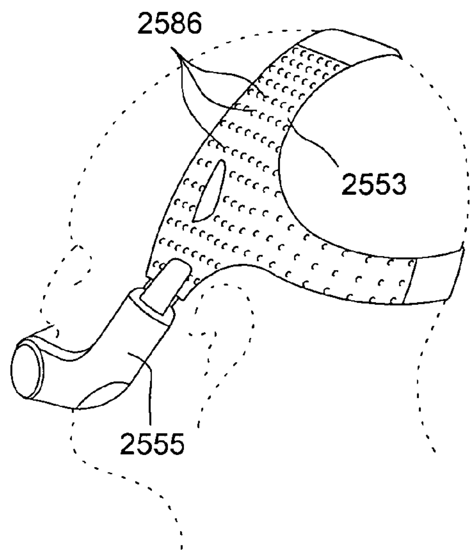


FIG. 12-6

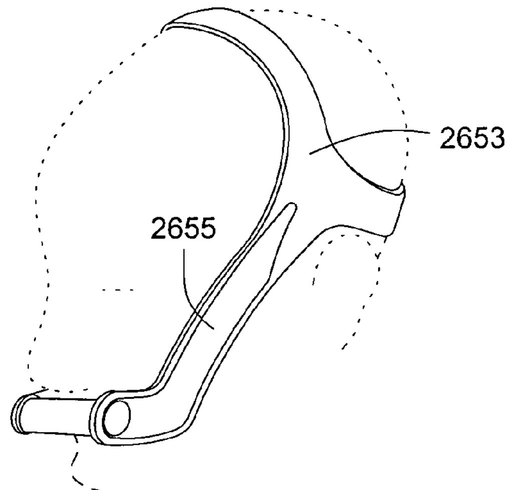


FIG. 12-7-1

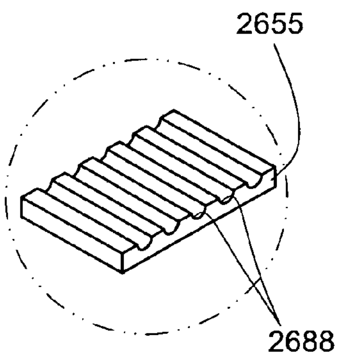


FIG. 12-7-2

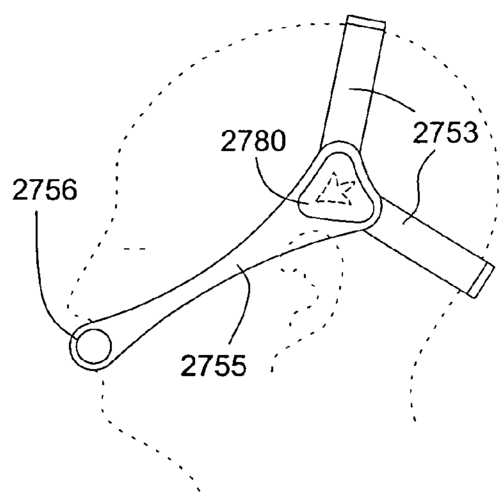


FIG. 12-8

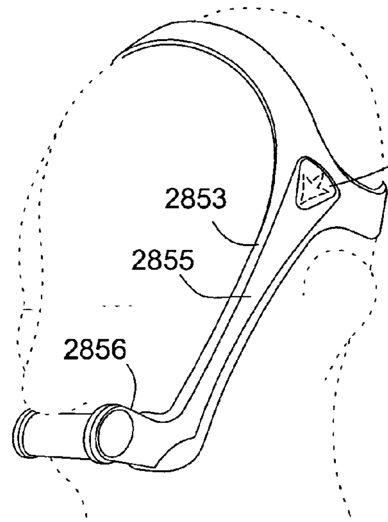


FIG. 12-9-1

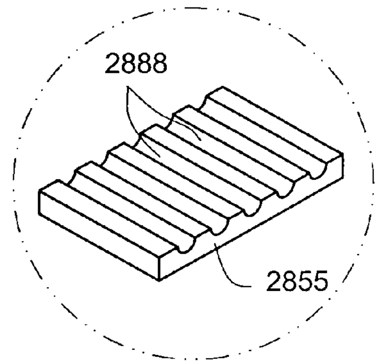


FIG. 12-9-2

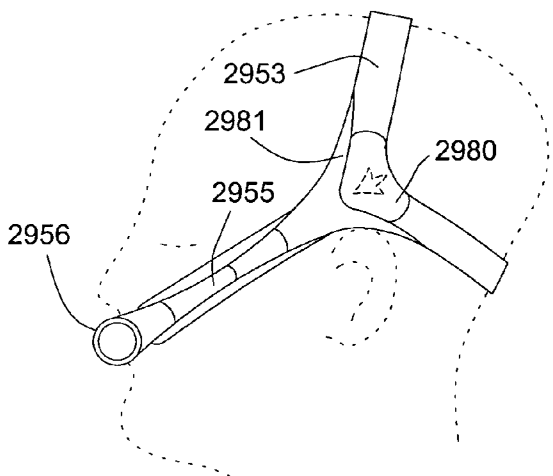


FIG. 12-10

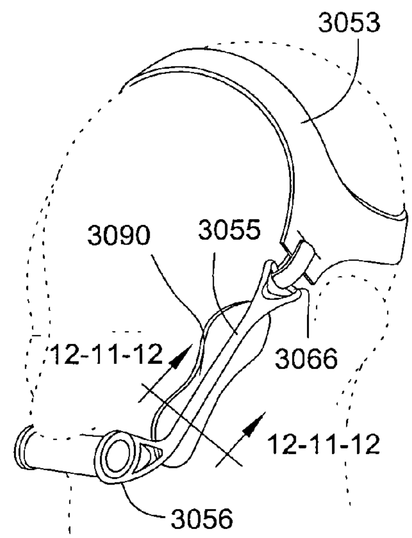


FIG. 12-11-1

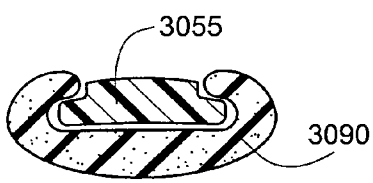


FIG. 12-11-2

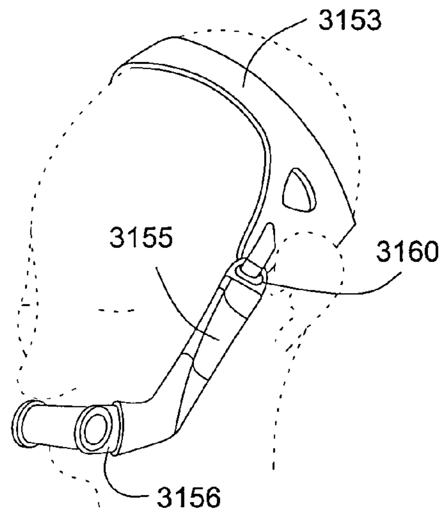


FIG. 12-12-1

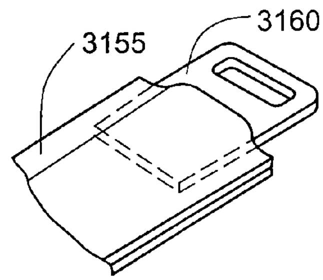


FIG. 12-12-2

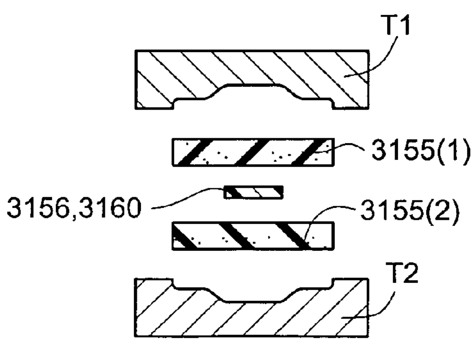


FIG. 12-12-3

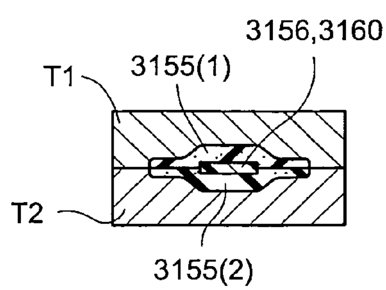


FIG. 12-12-4

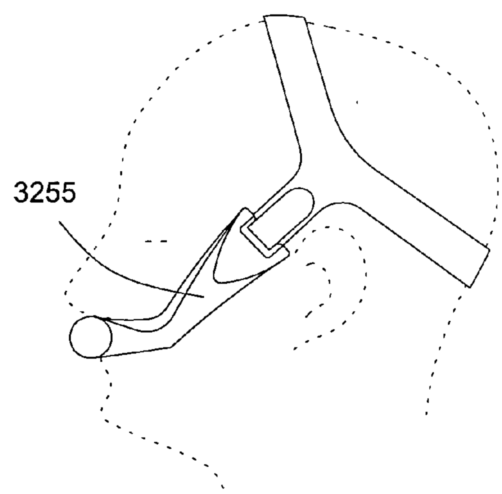


FIG. 12-13

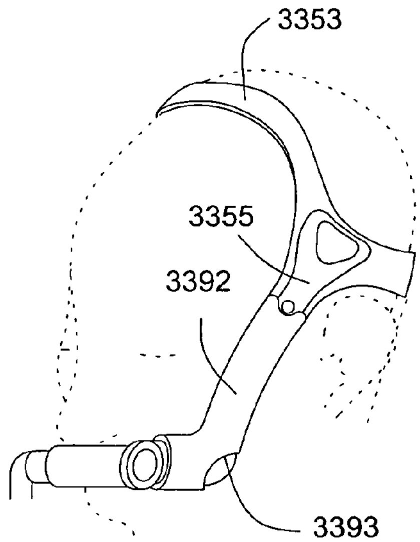


FIG. 12-14-1

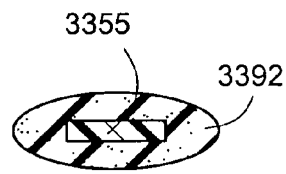


FIG. 12-14-2

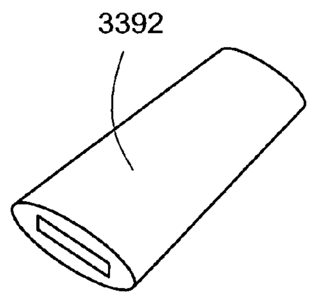


FIG. 12-14-3

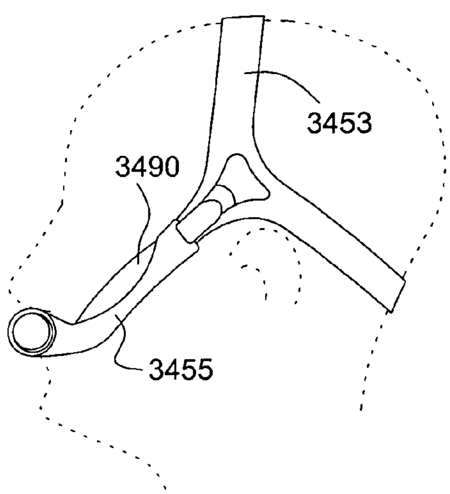
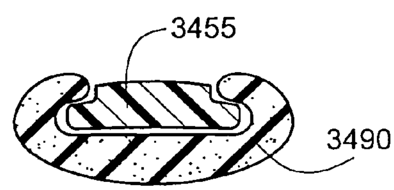


FIG. 12-15-1



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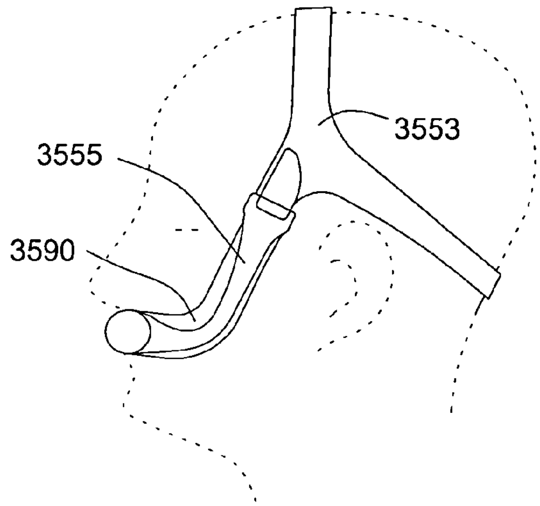
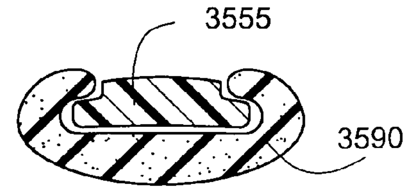


FIG. 12-16-1



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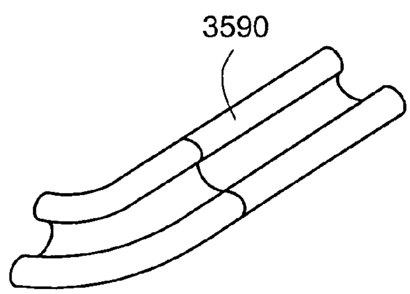

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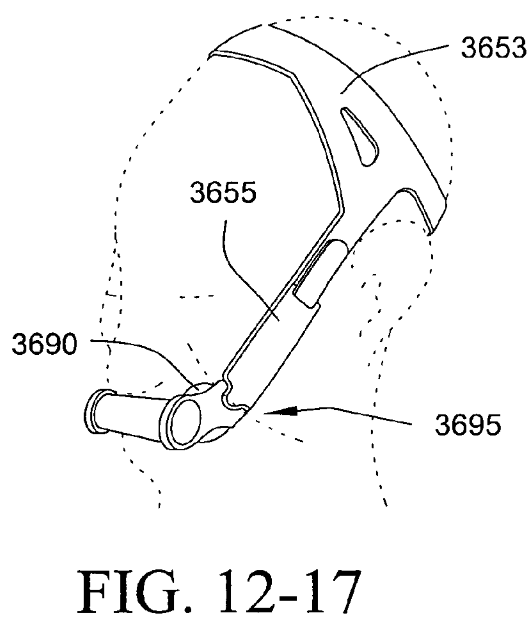
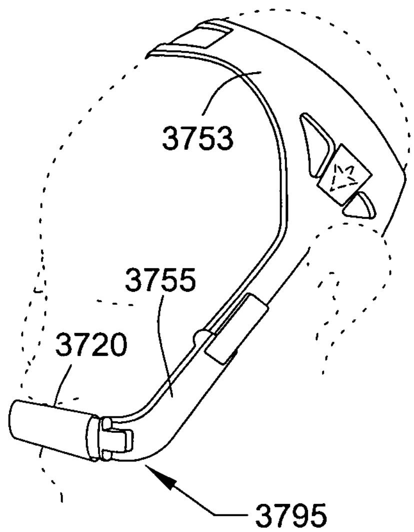


FIG. 12-17



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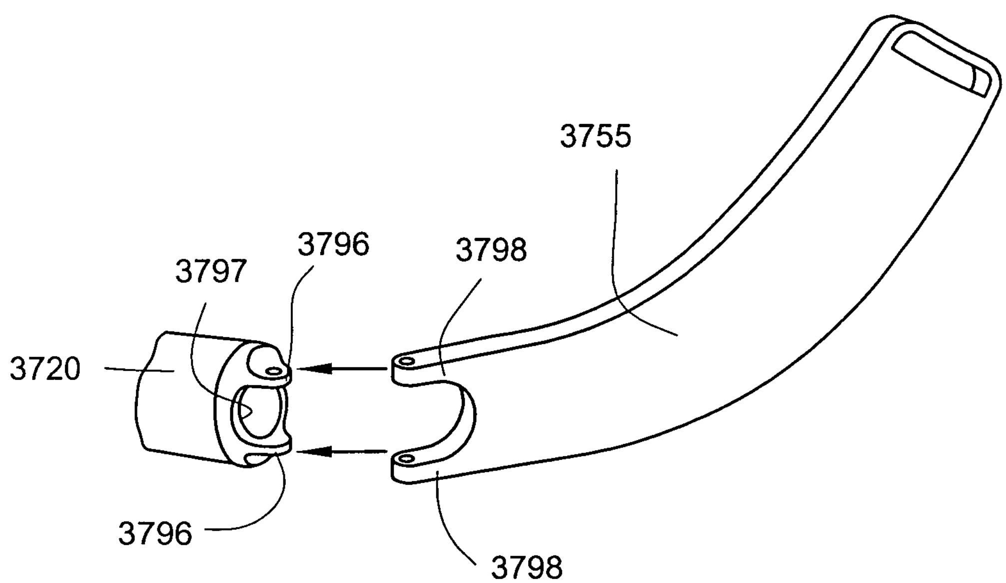
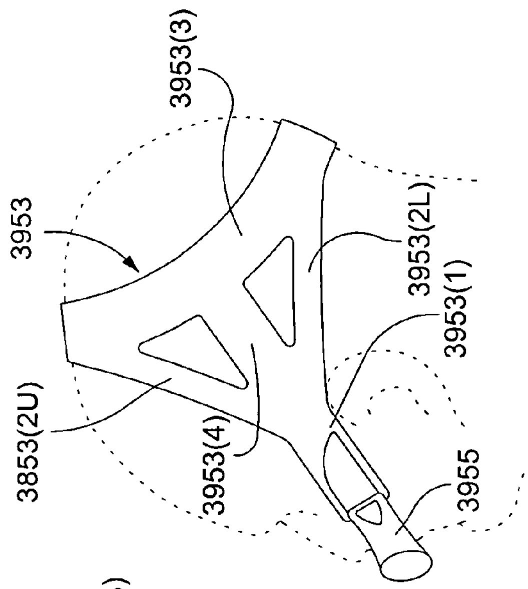


FIG. 12-18-2



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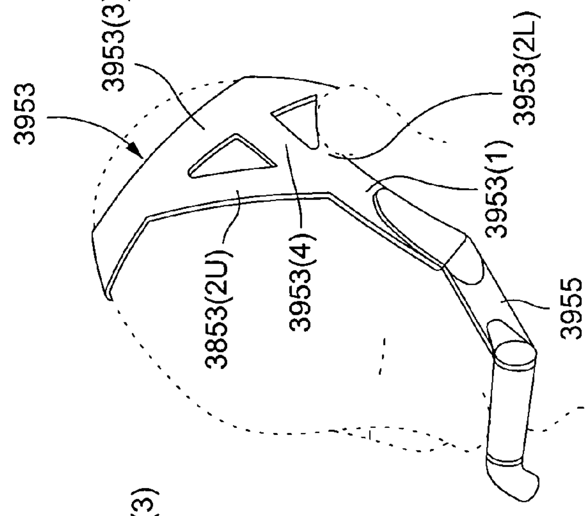


FIG. 12-20-1

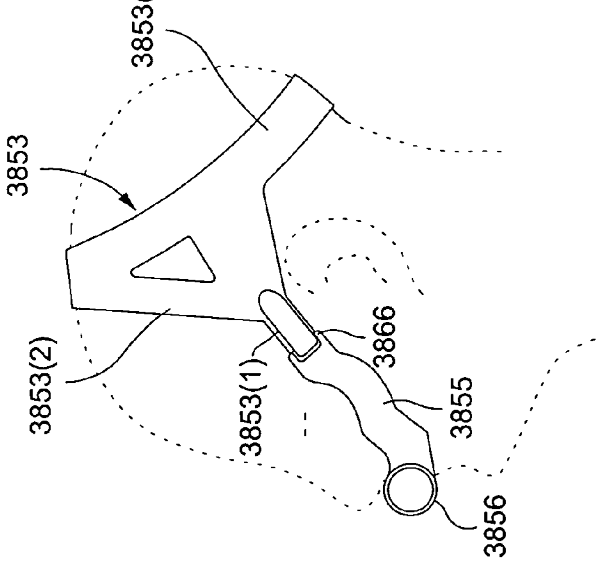
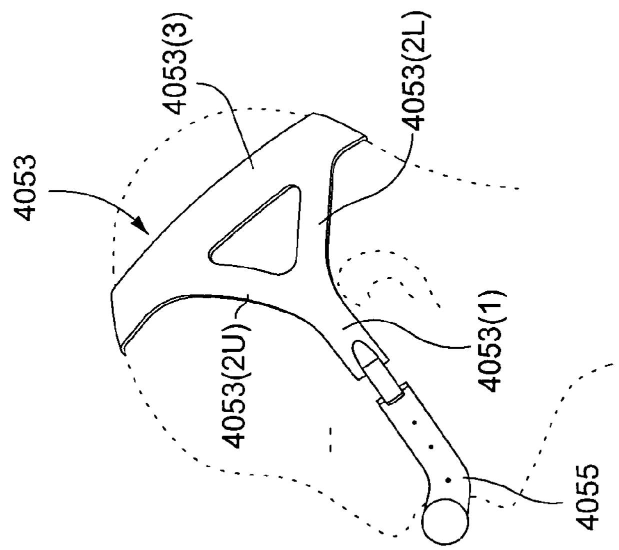


FIG. 12-19



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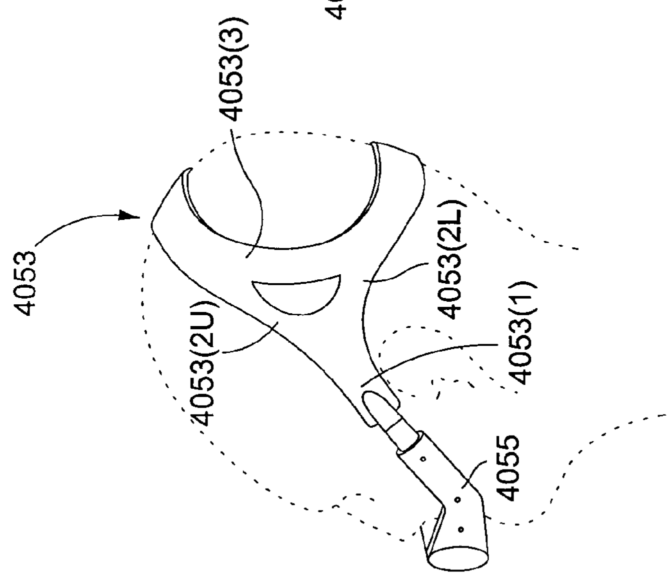


FIG. 12-21-2

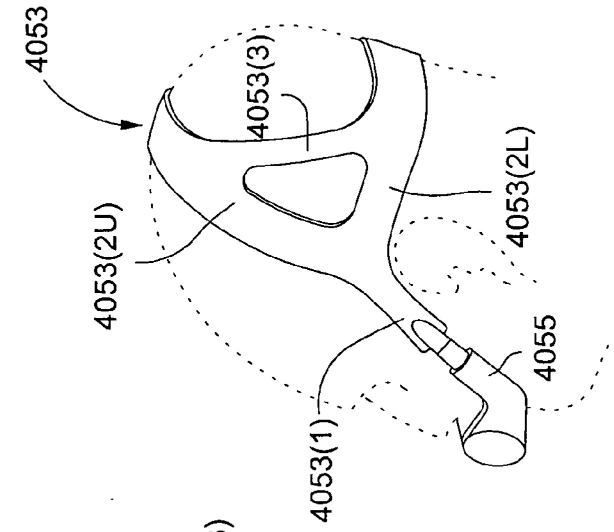


FIG. 12-21-3

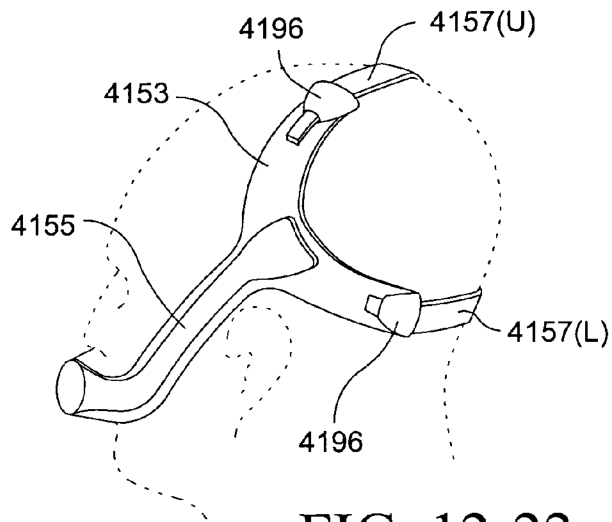
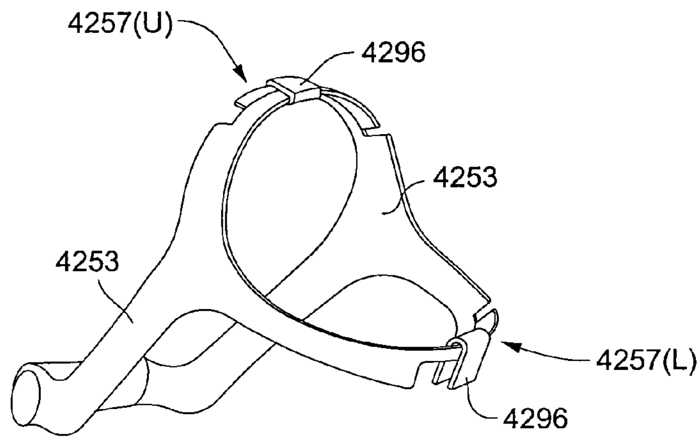


FIG. 12-22



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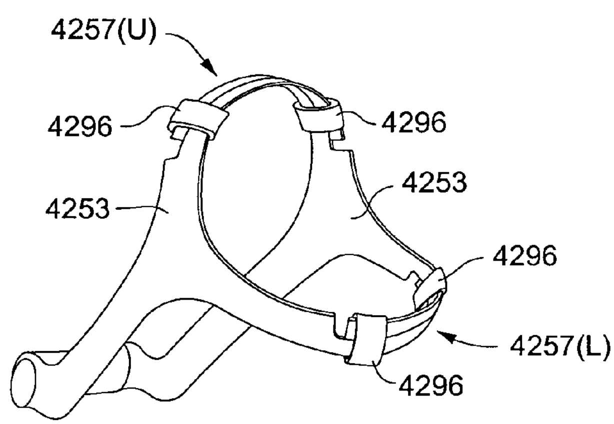

FIG. 12-23-2

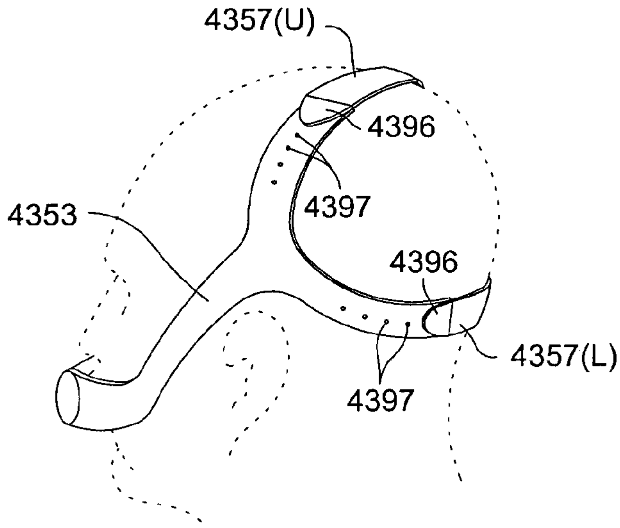

FIG. 12-24-1

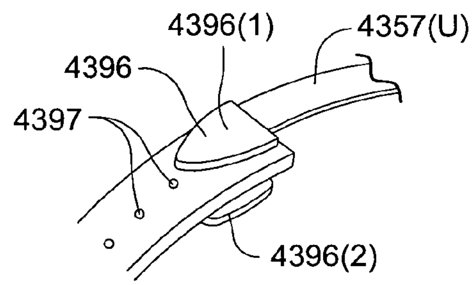

FIG. 12-24-2

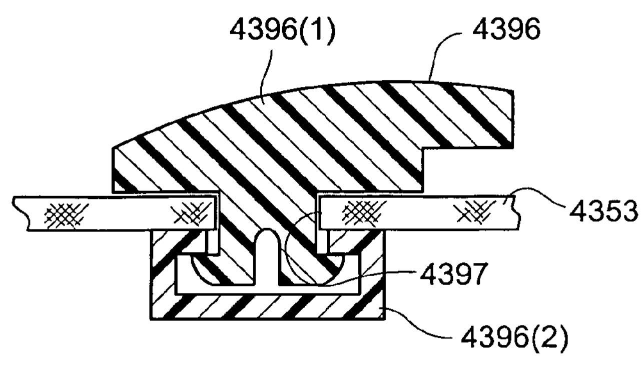

FIG. 12-24-3

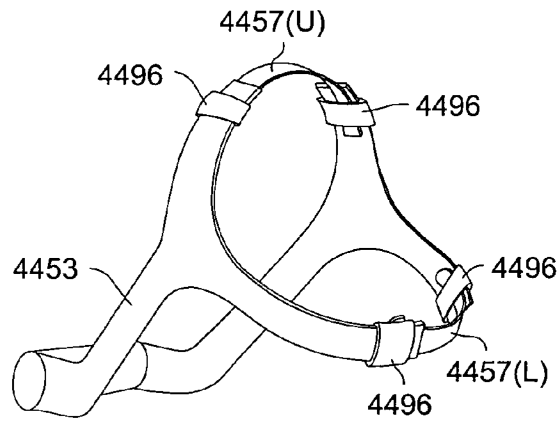

FIG. 12-25-1

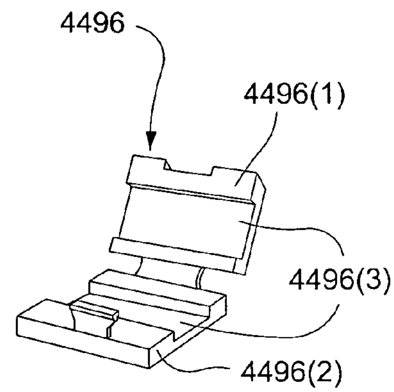

FIG. 12-25-2

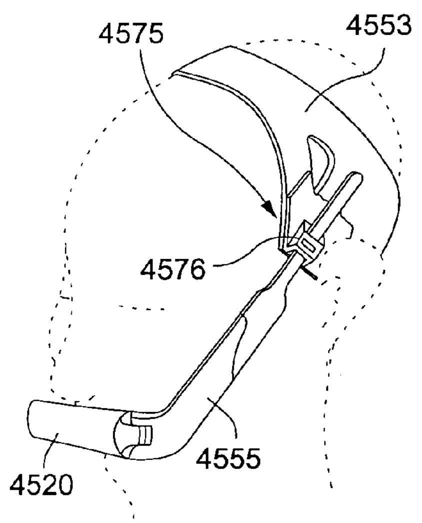

FIG. 12-26-1

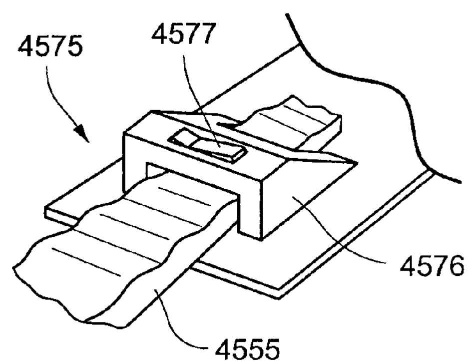

FIG. 12-26-2

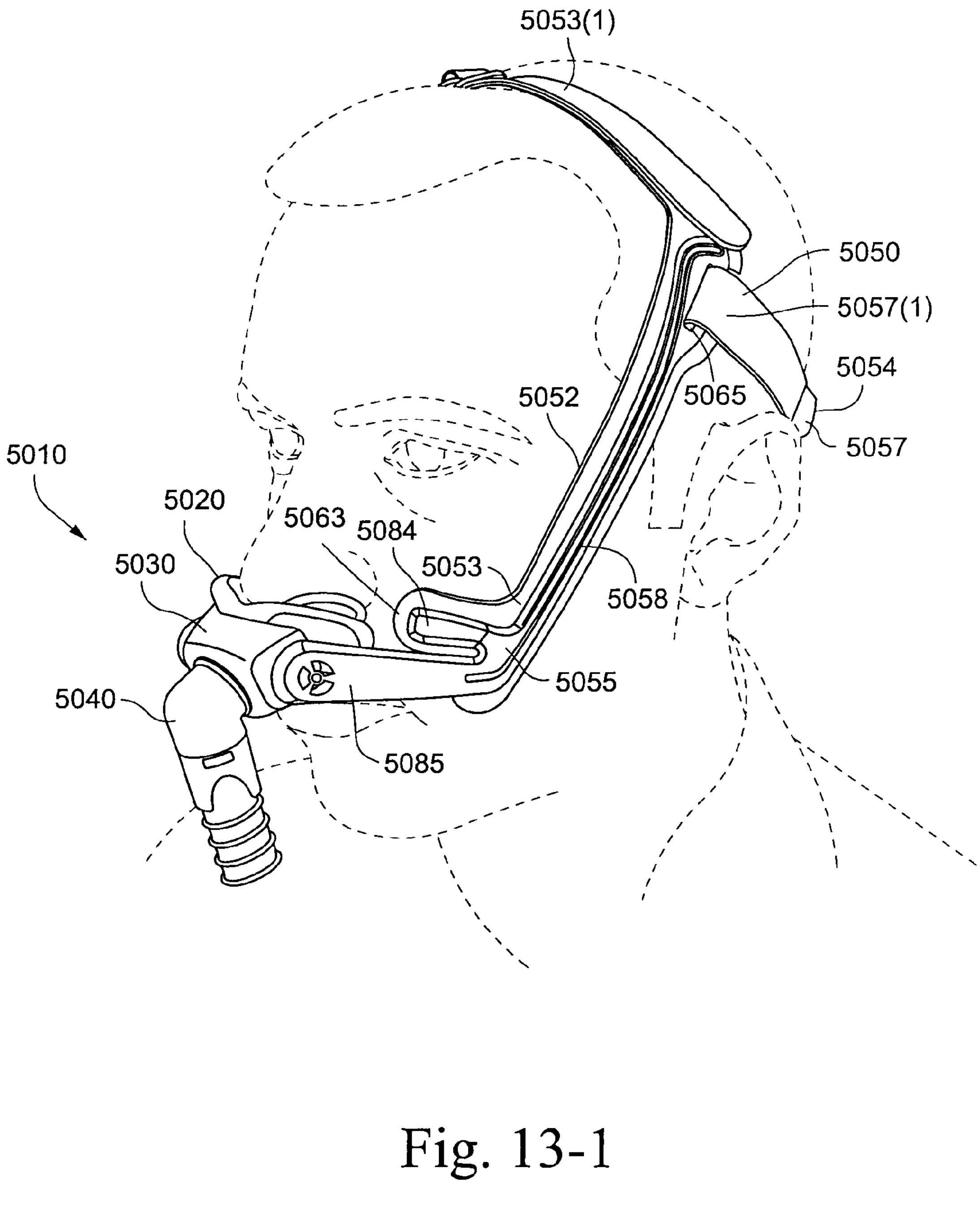

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Fig. 13-1

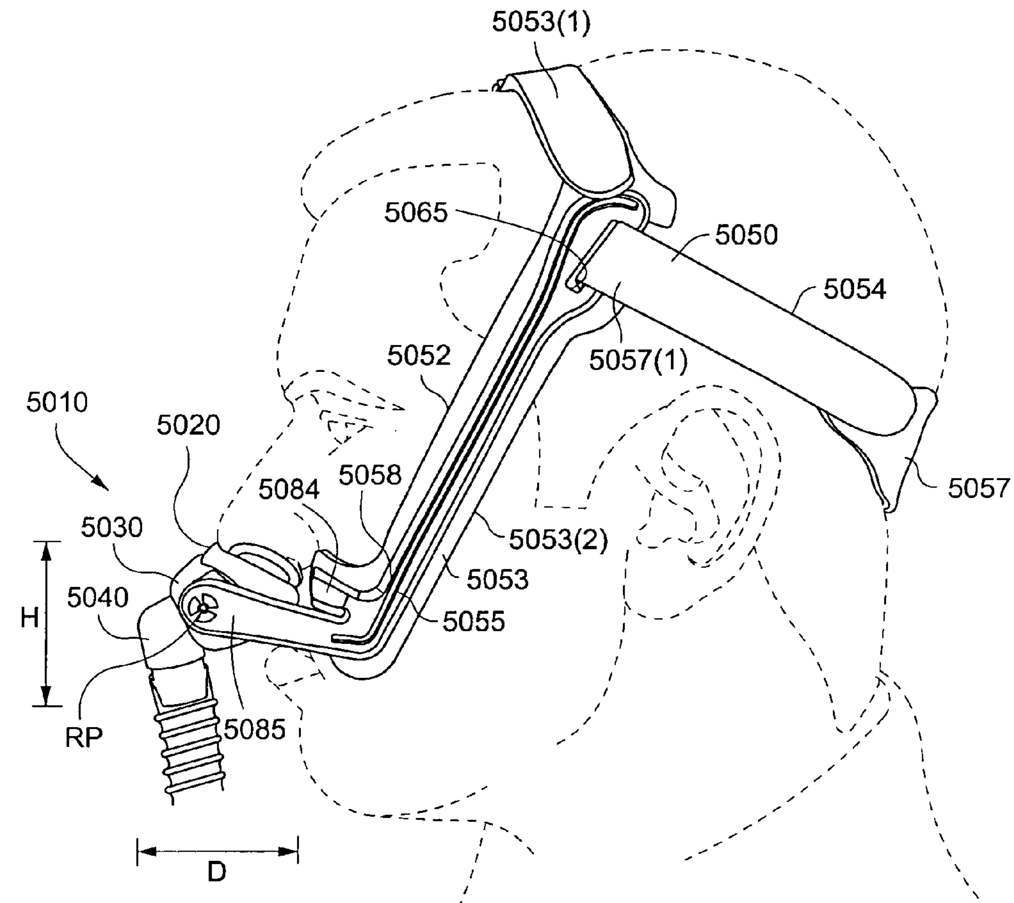
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Fig. 13-2

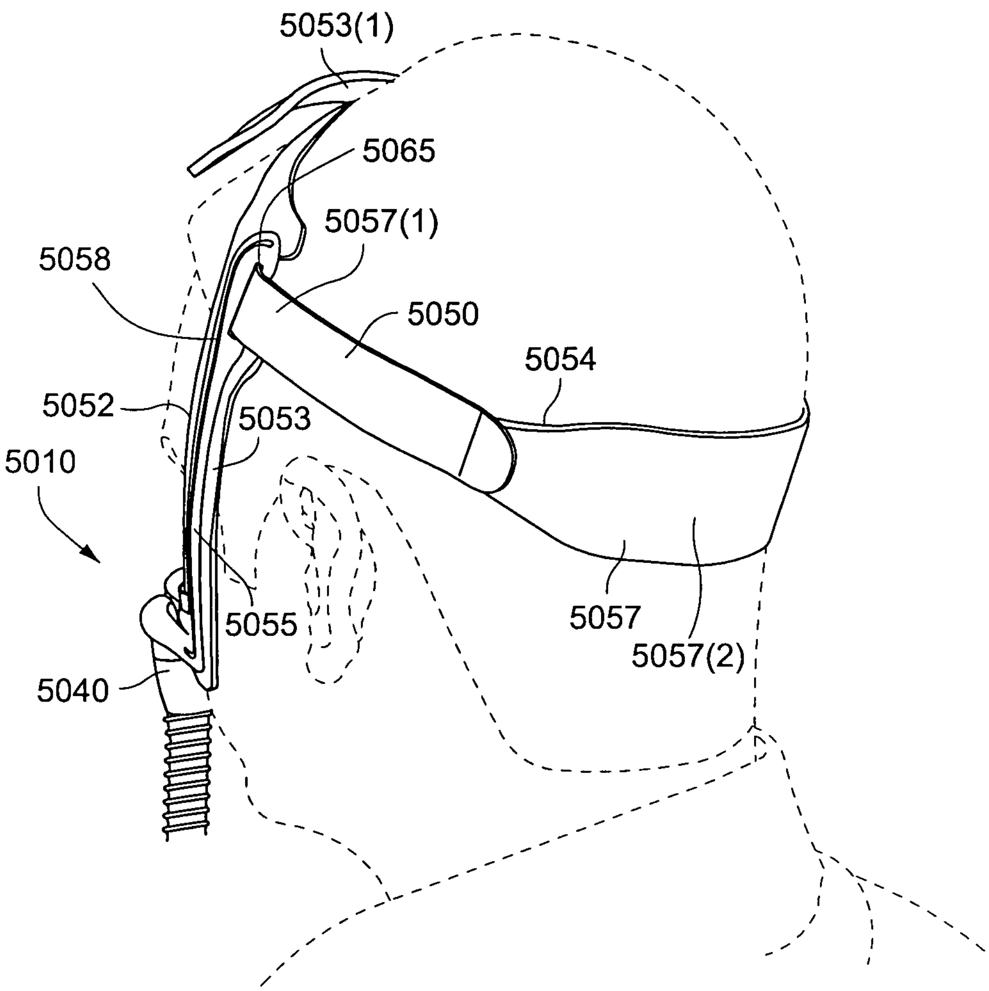
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Fig. 13-3

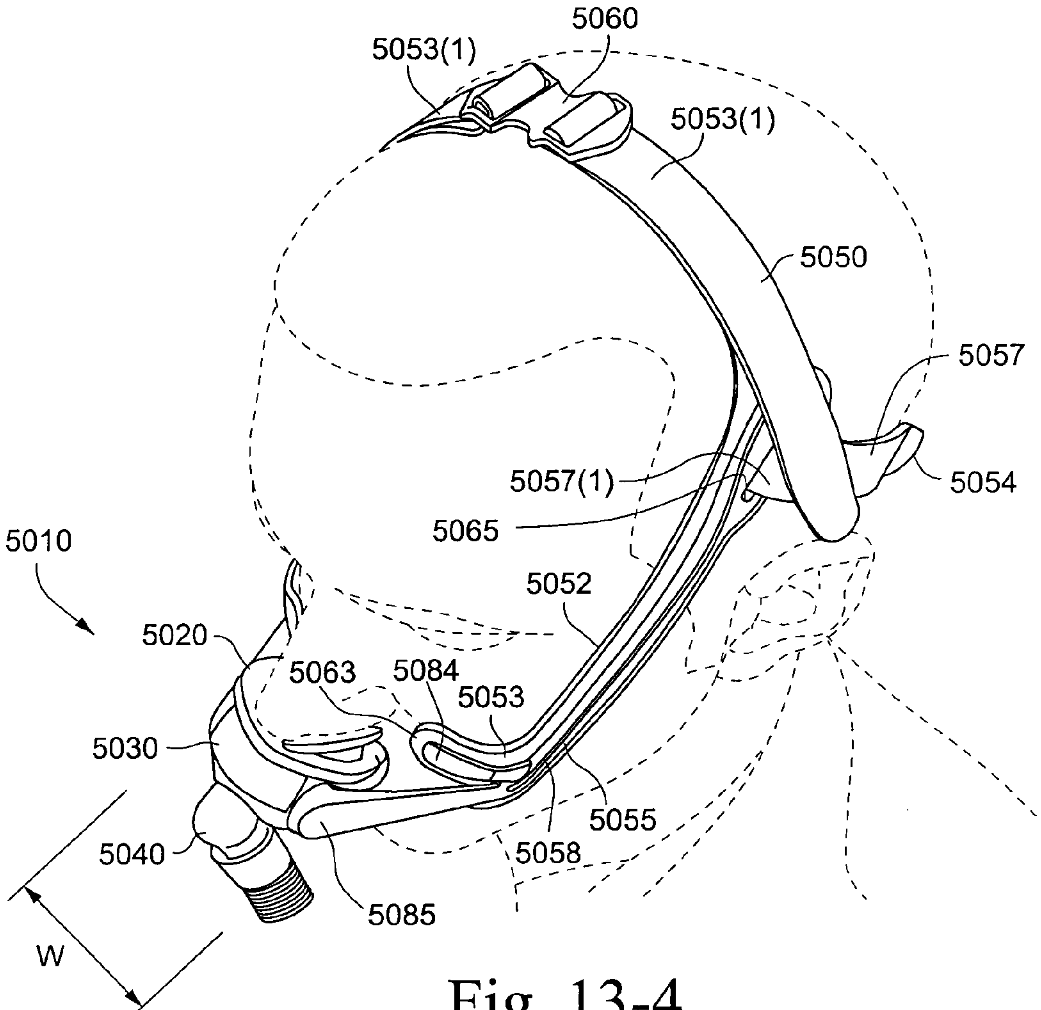

Fig. 13-4

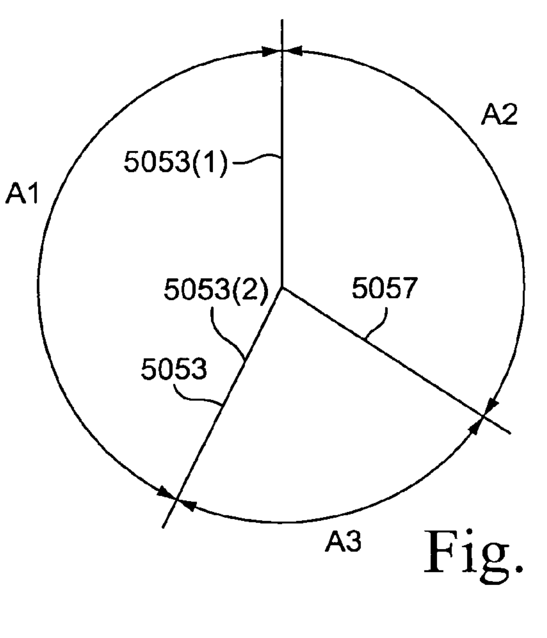

Fig. 13-5

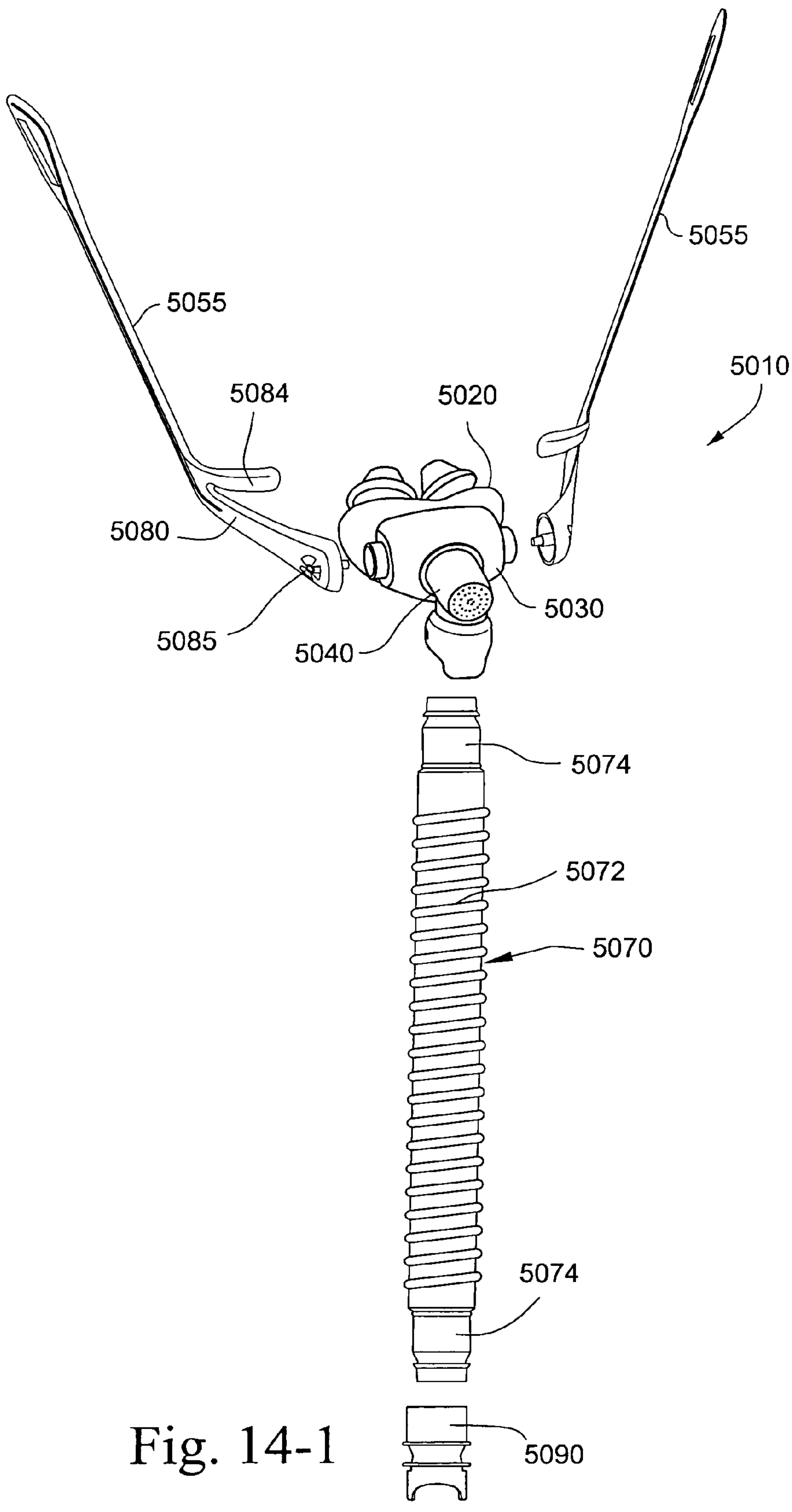
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Fig. 14-1

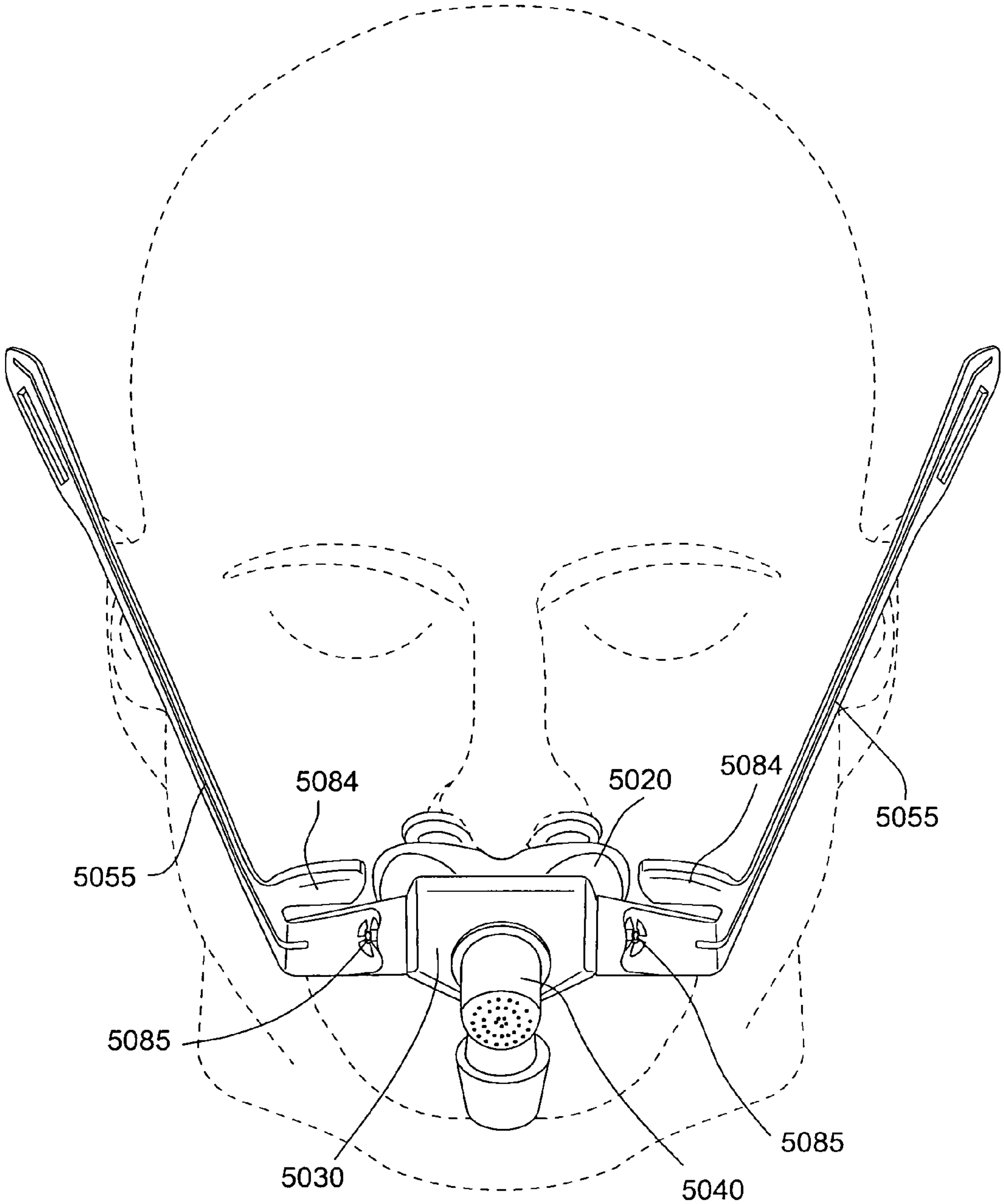


Fig. 14-2

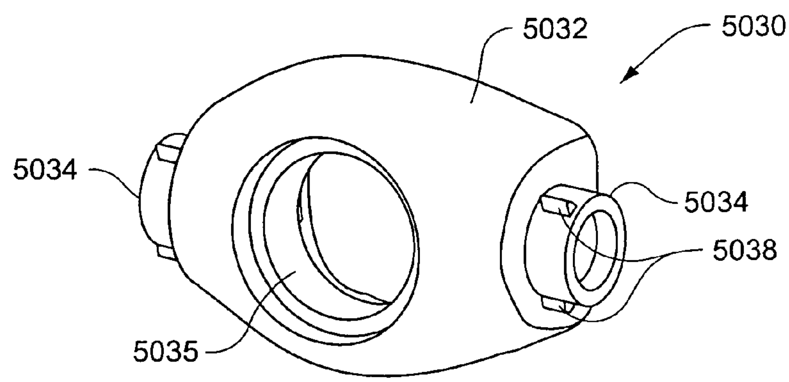
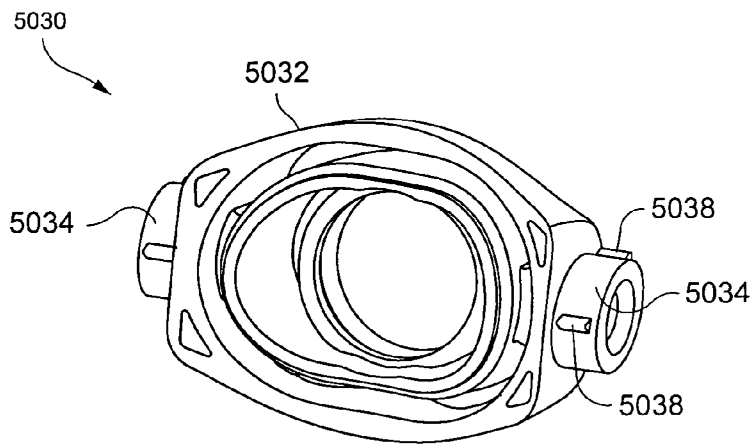


Fig. 15-1



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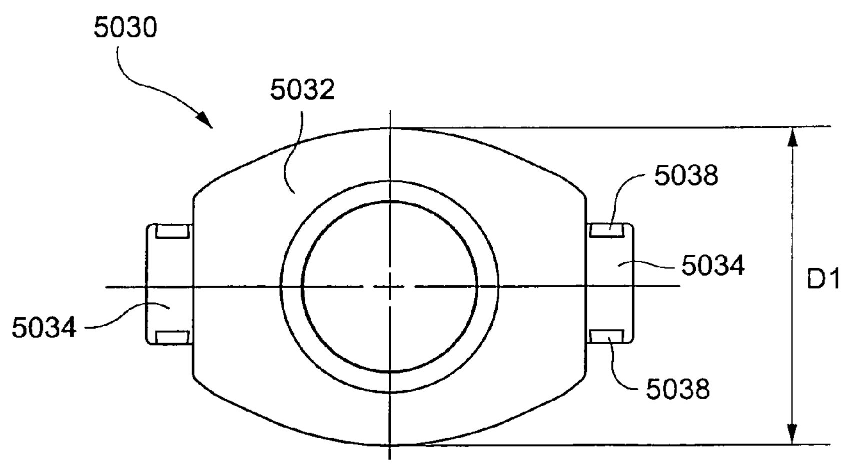
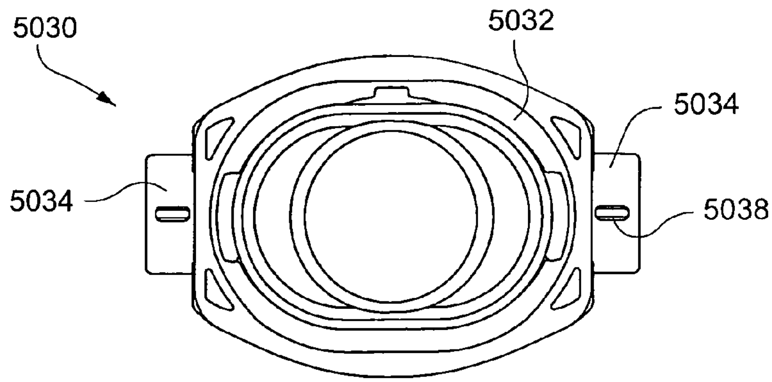


Fig. 15-3



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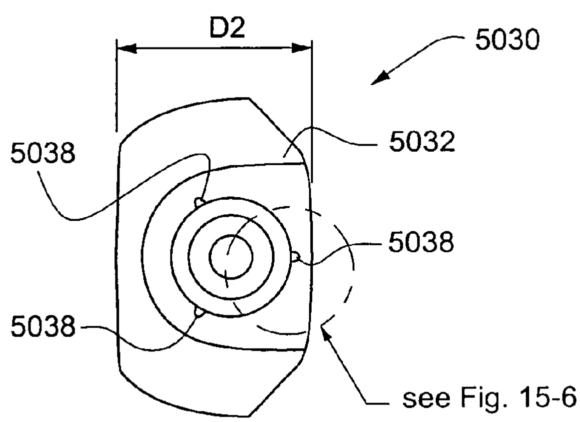


Fig. 15-5

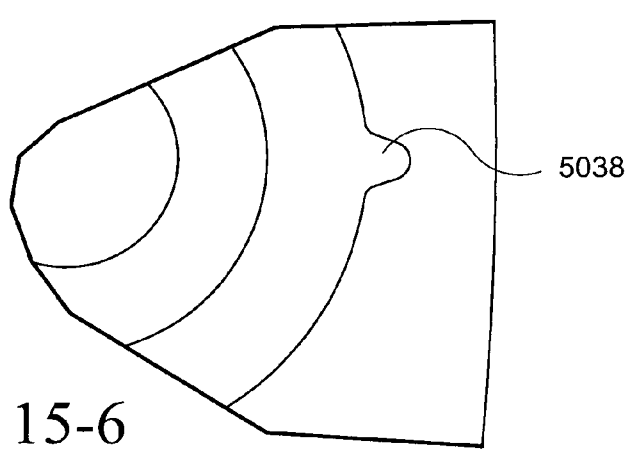


Fig. 15-6

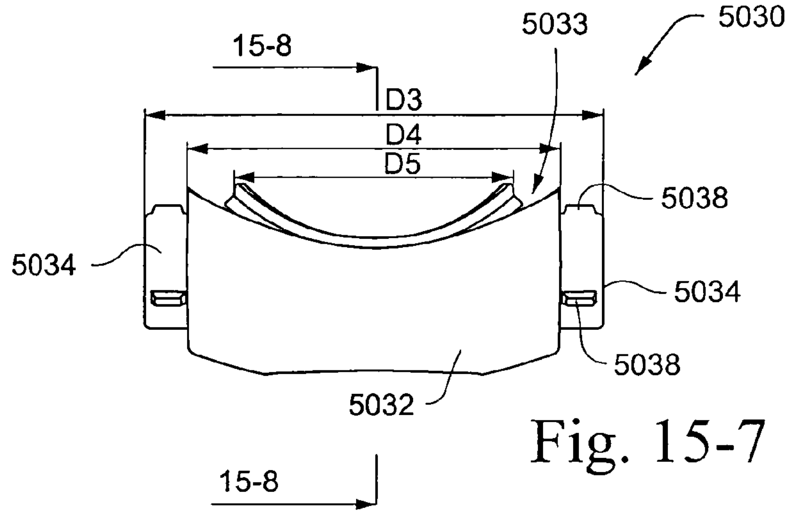


Fig. 15-7

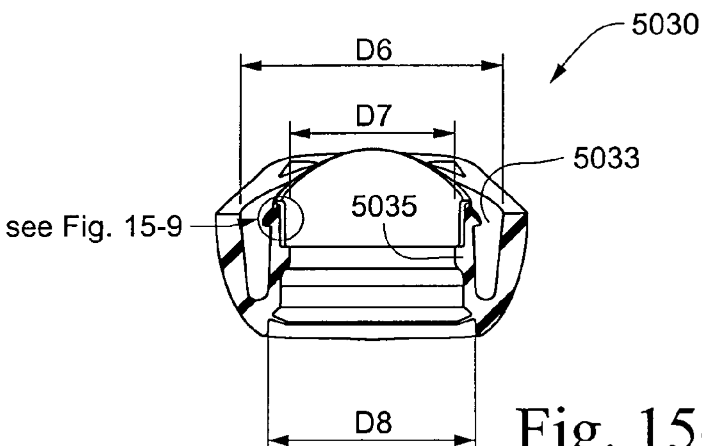


Fig. 15-8

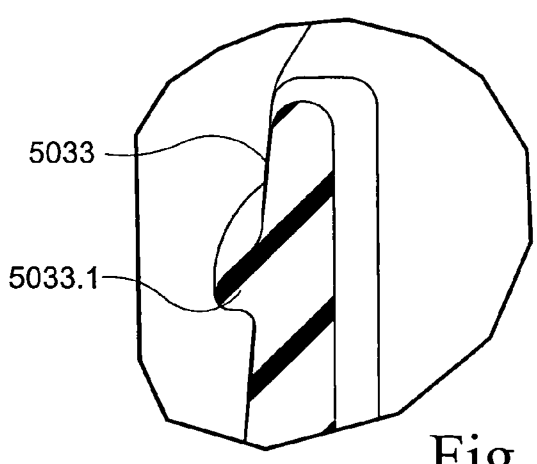


Fig. 15-9

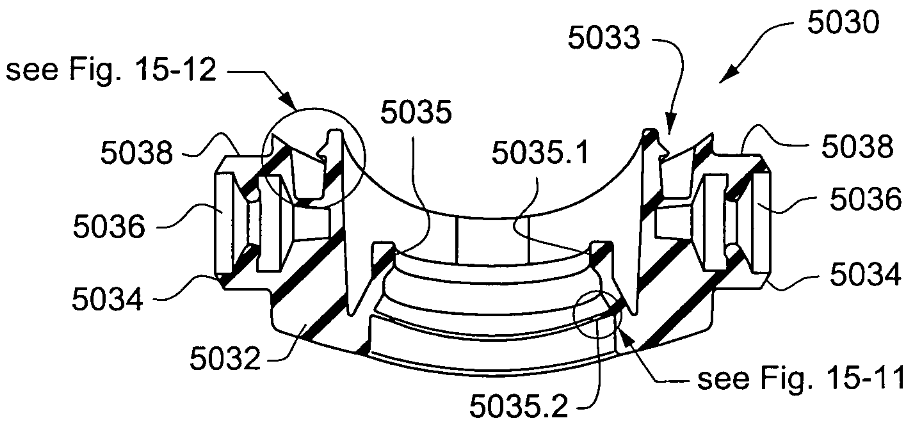


Fig. 15-10

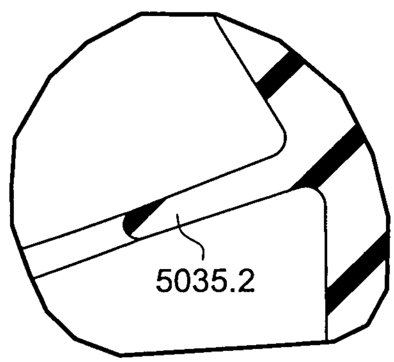


Fig. 15-11

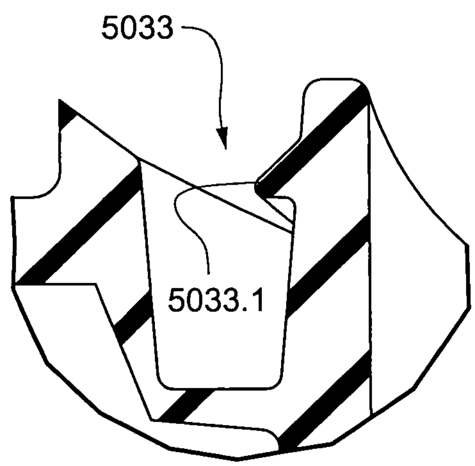


Fig. 15-12

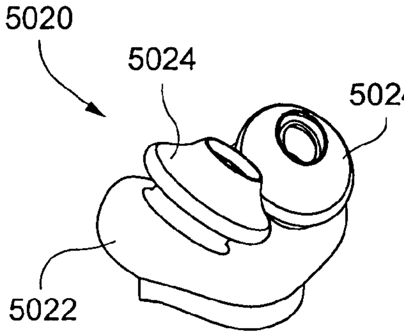


Fig. 16-1

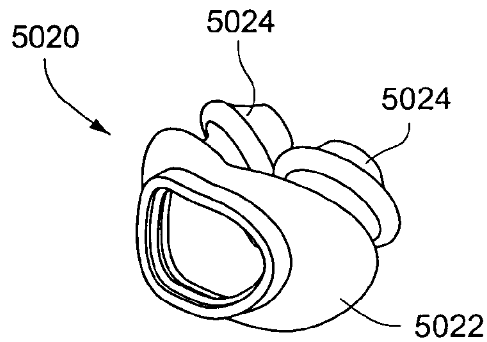


Fig. 16-2

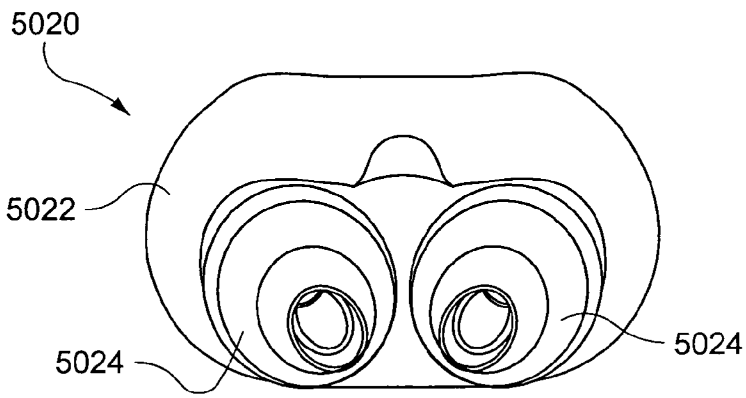


Fig. 16-3

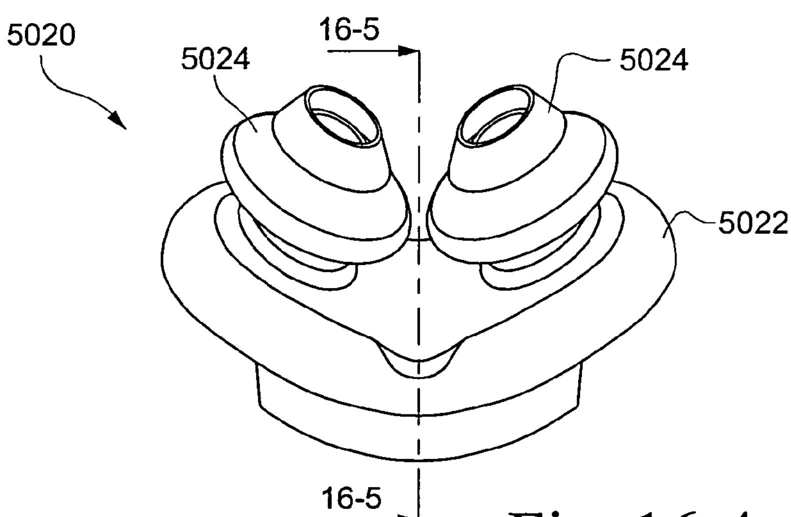


Fig. 16-4

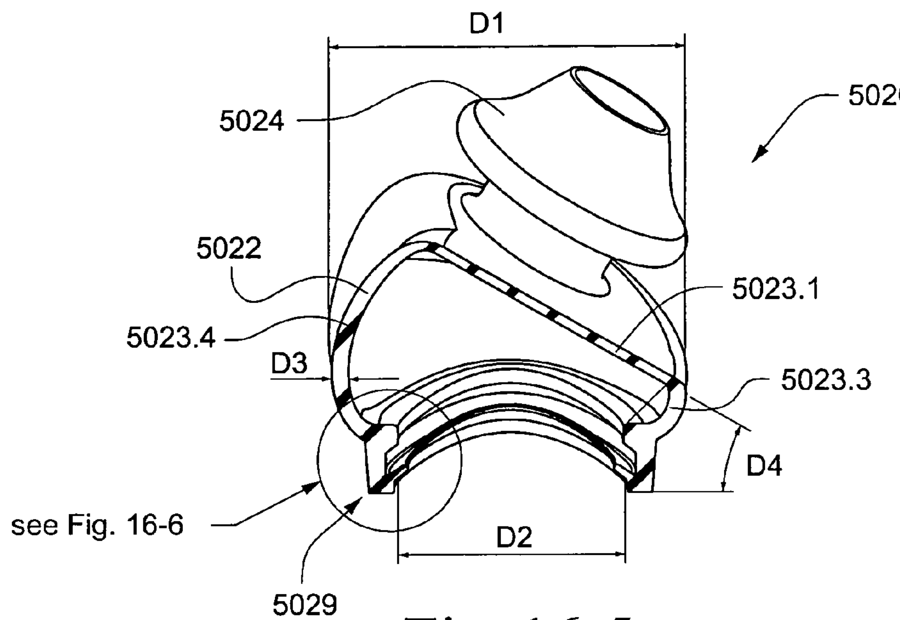


Fig. 16-5

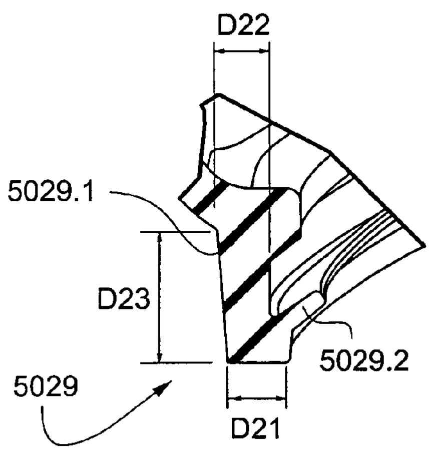


Fig. 16-6

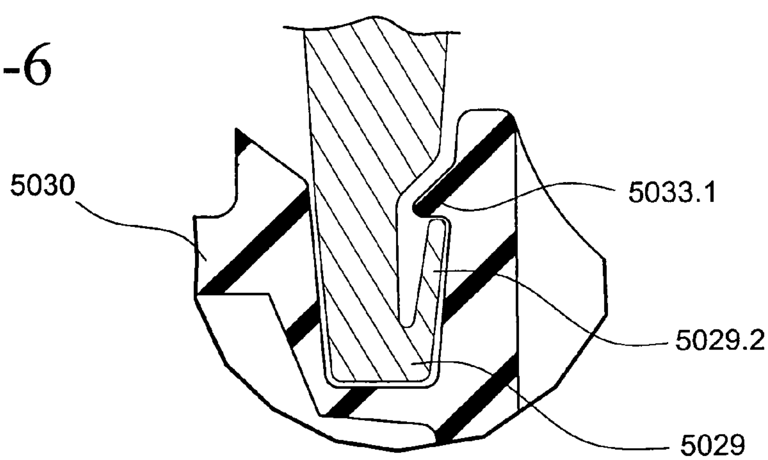


Fig. 16-6-1

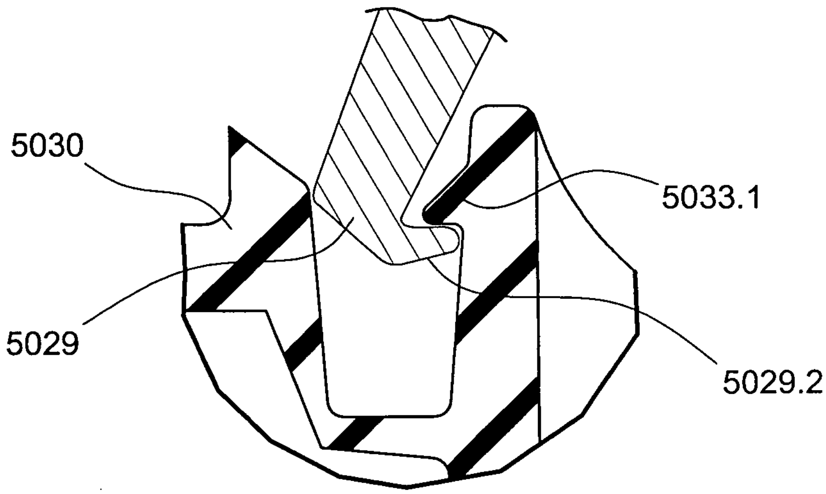


Fig. 16-6-2

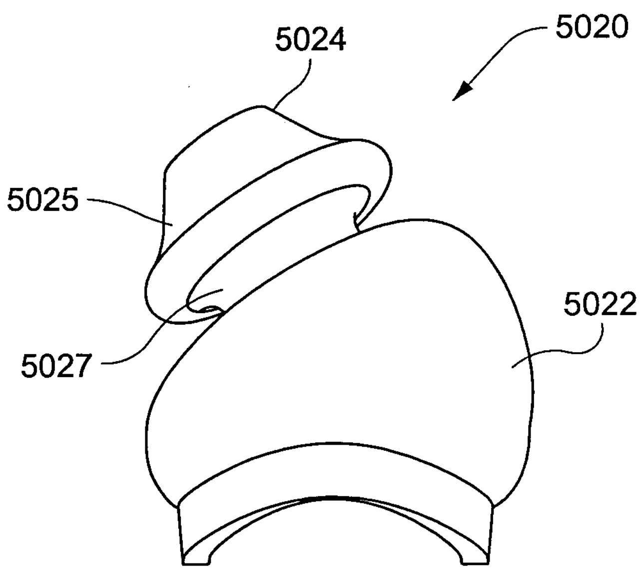


Fig. 16-7

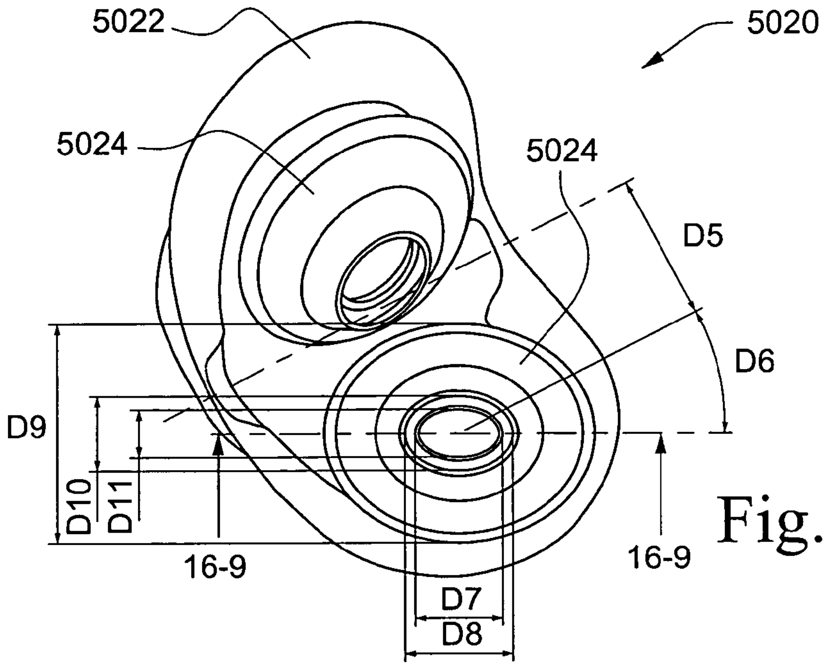
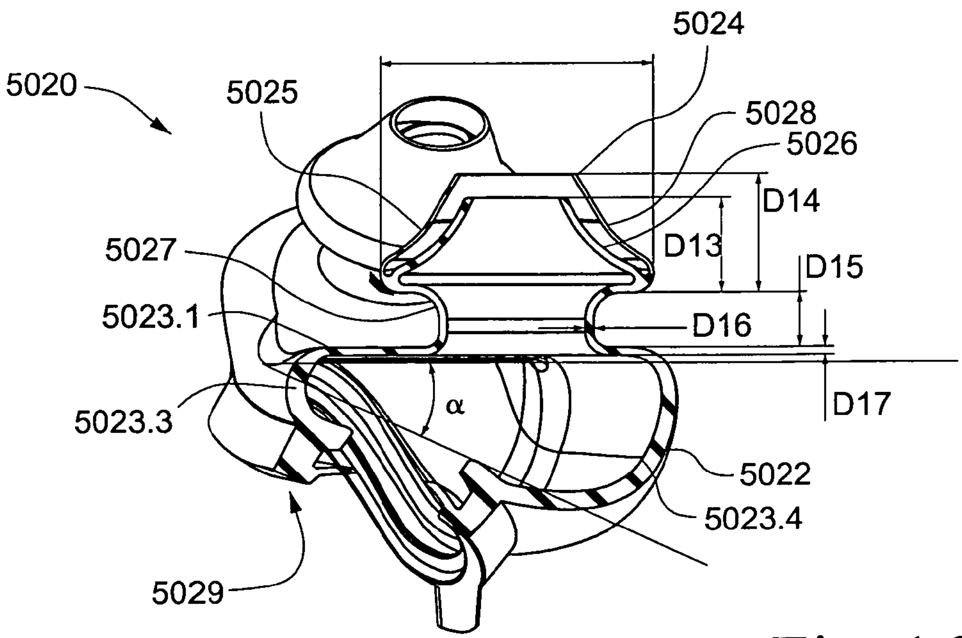


Fig. 16-8



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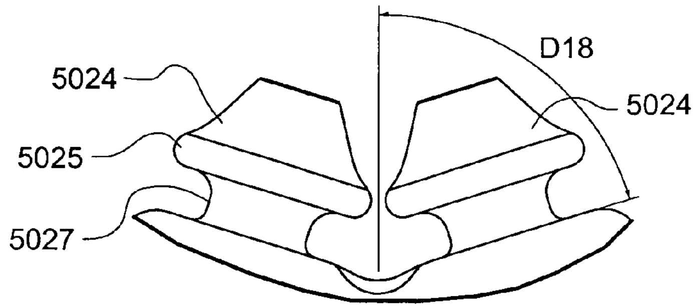

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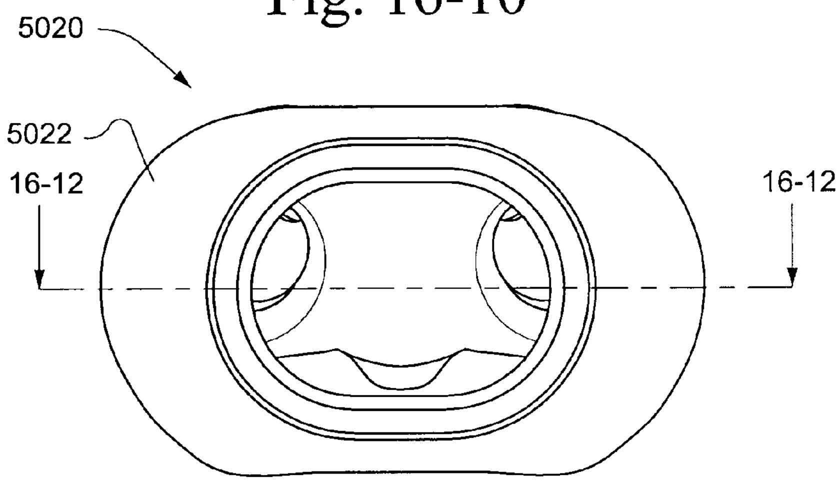


Fig. 16-11

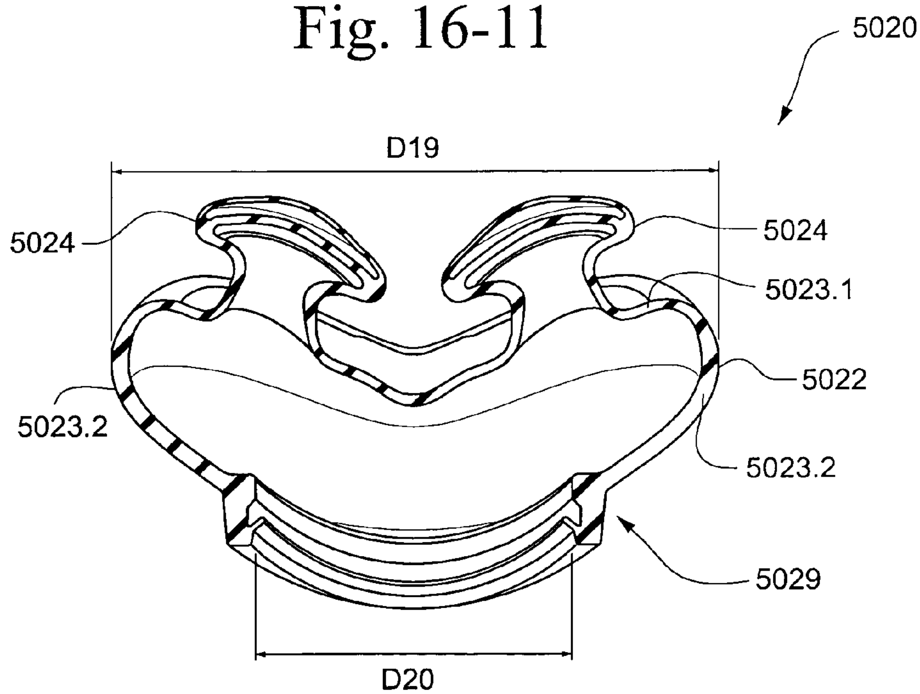


Fig. 16-12

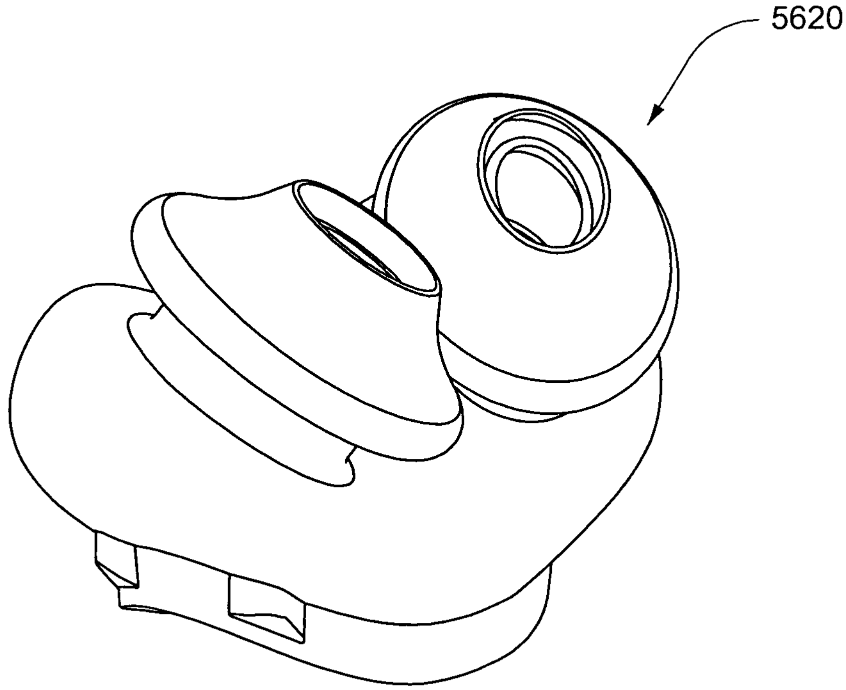


Fig. 16-13-1

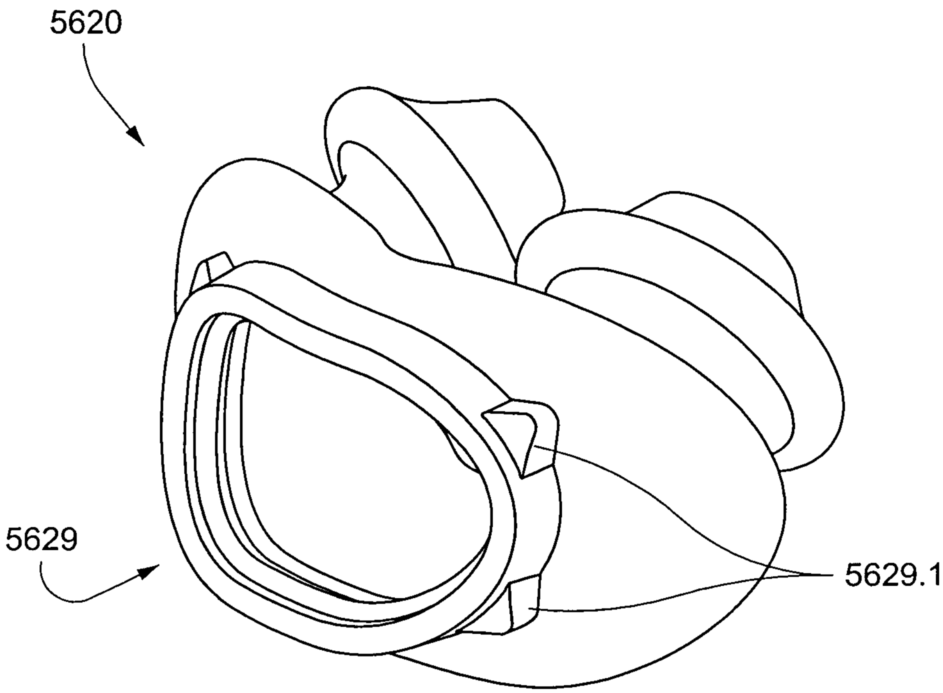


Fig. 16-13-2

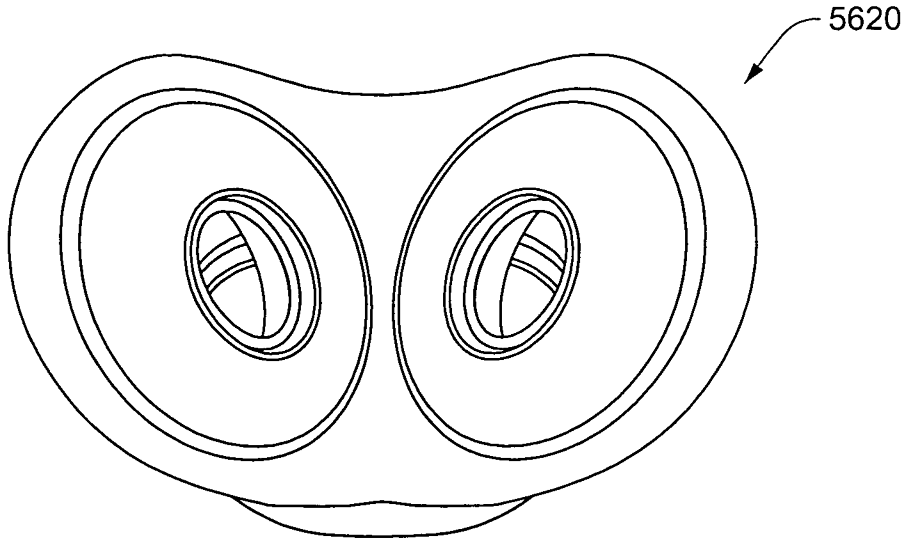


Fig. 16-13-3

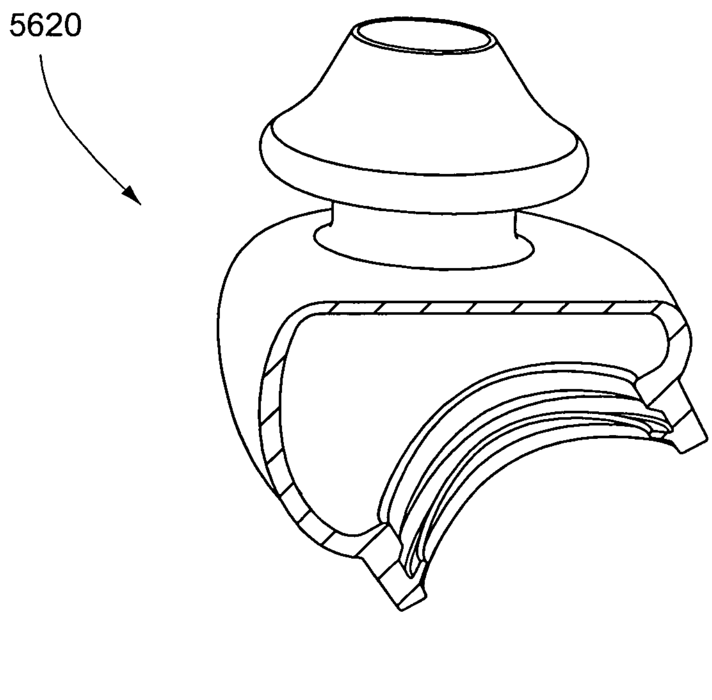


Fig. 16-13-4

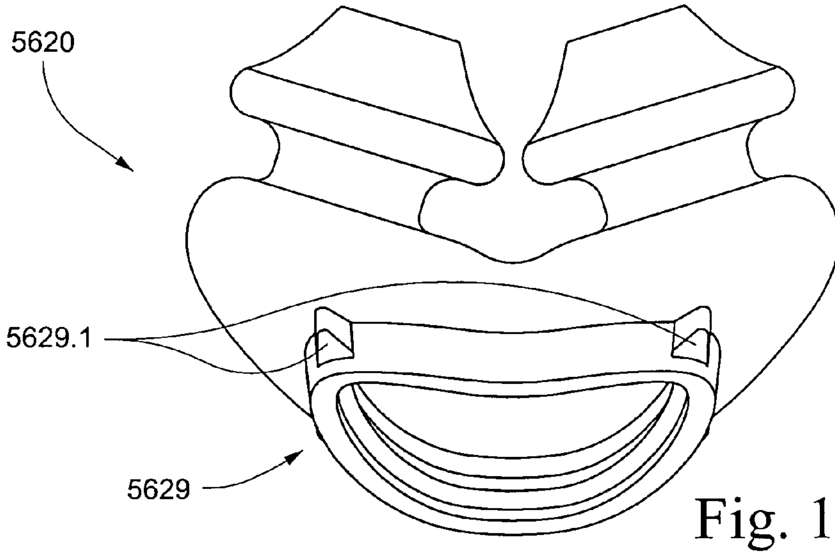


Fig. 16-13-5

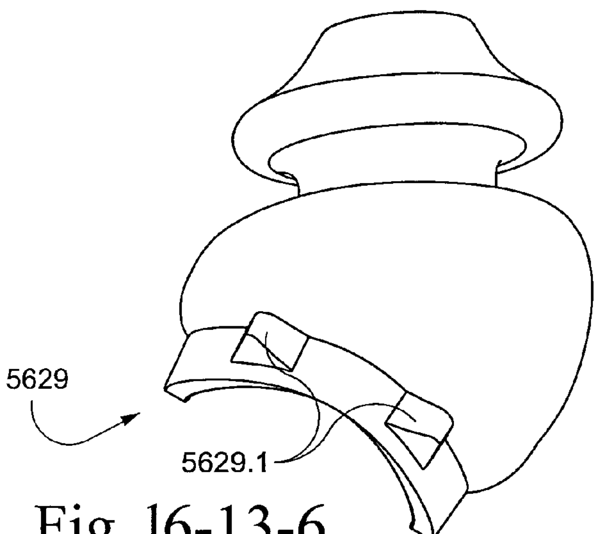


Fig. 16-13-6

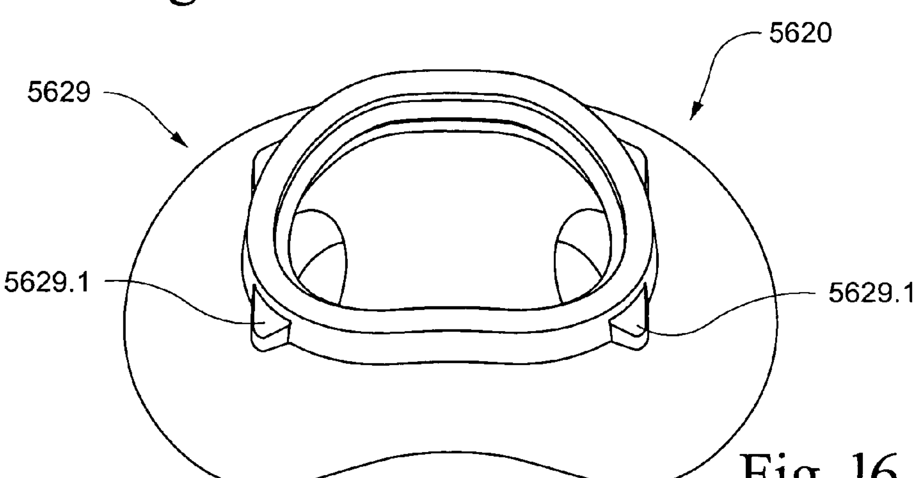


Fig. 16-13-7

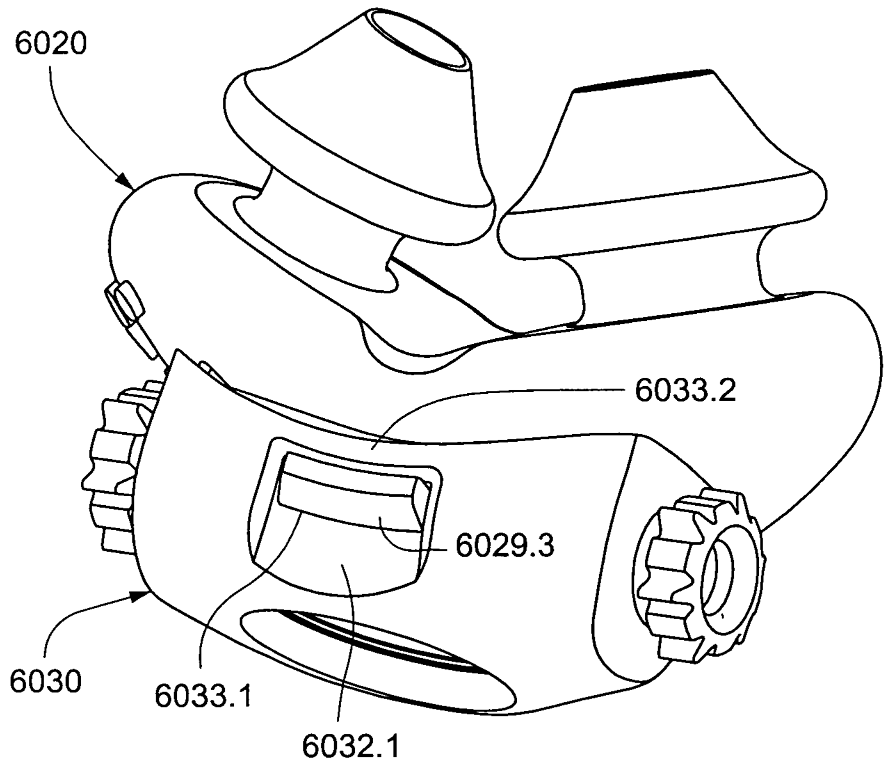


Fig. 16-14-1

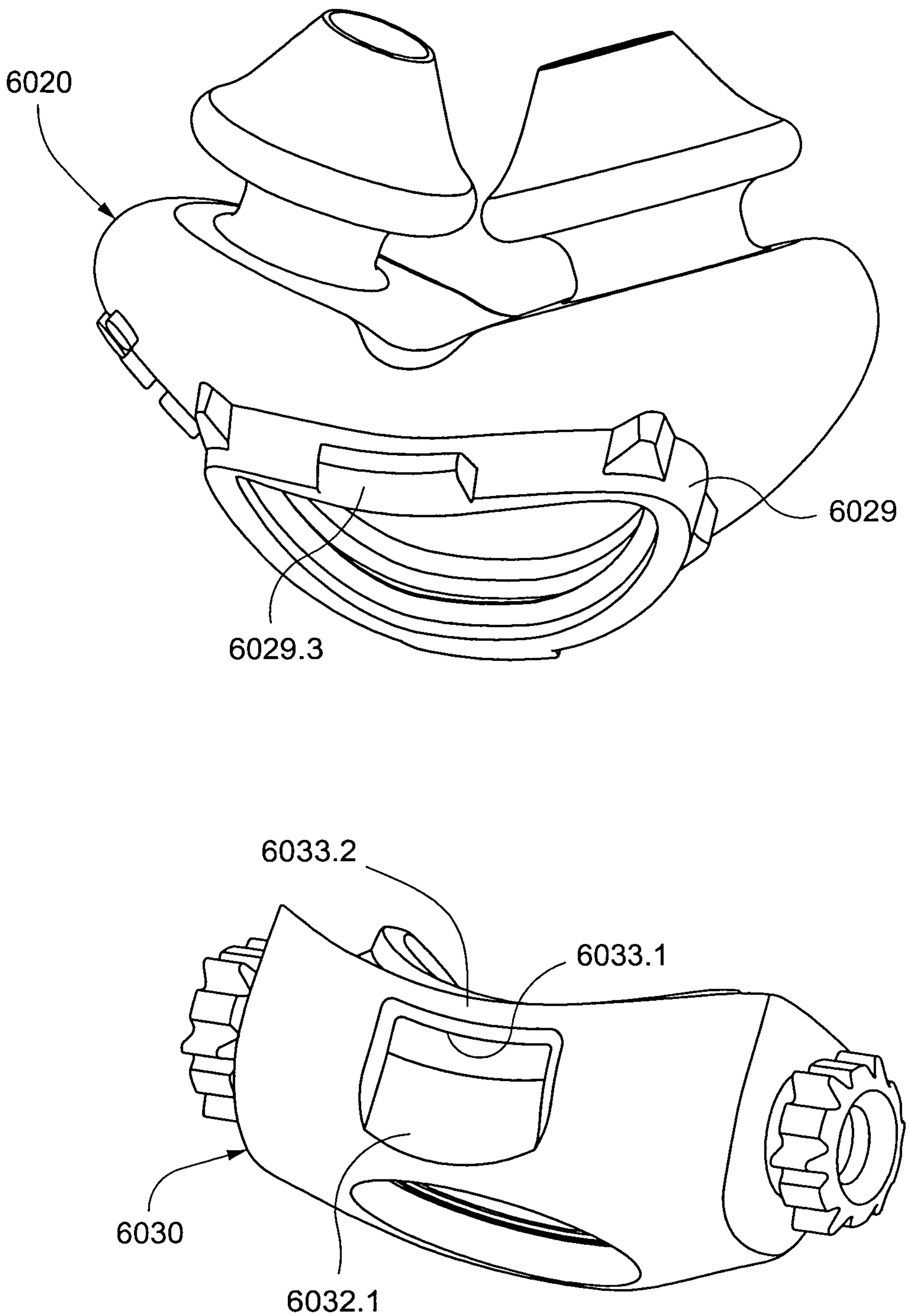


Fig. 16-14-2

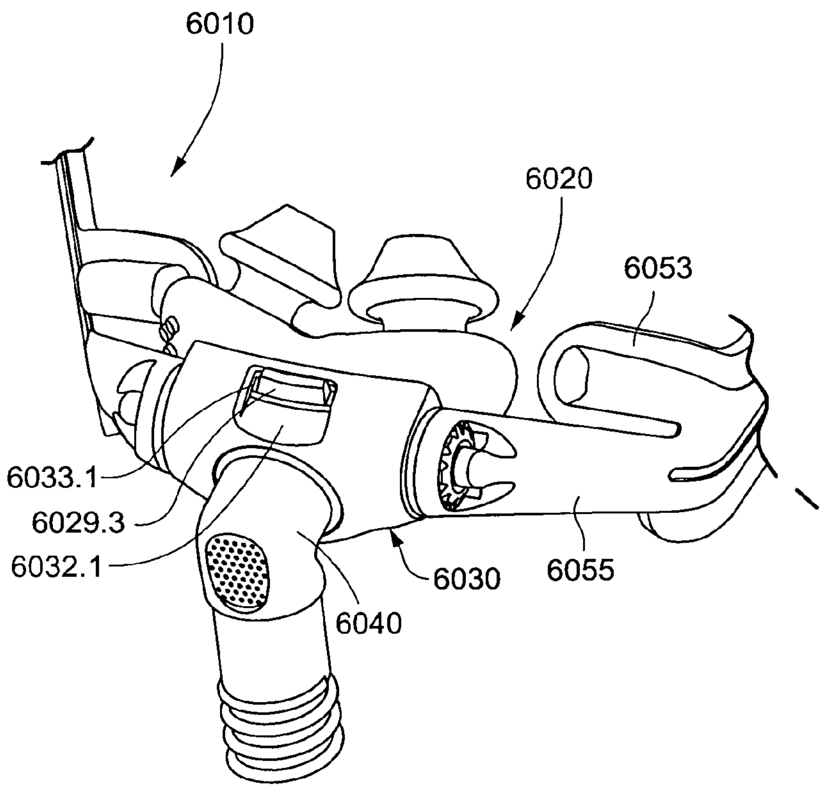


Fig. 16-14-3

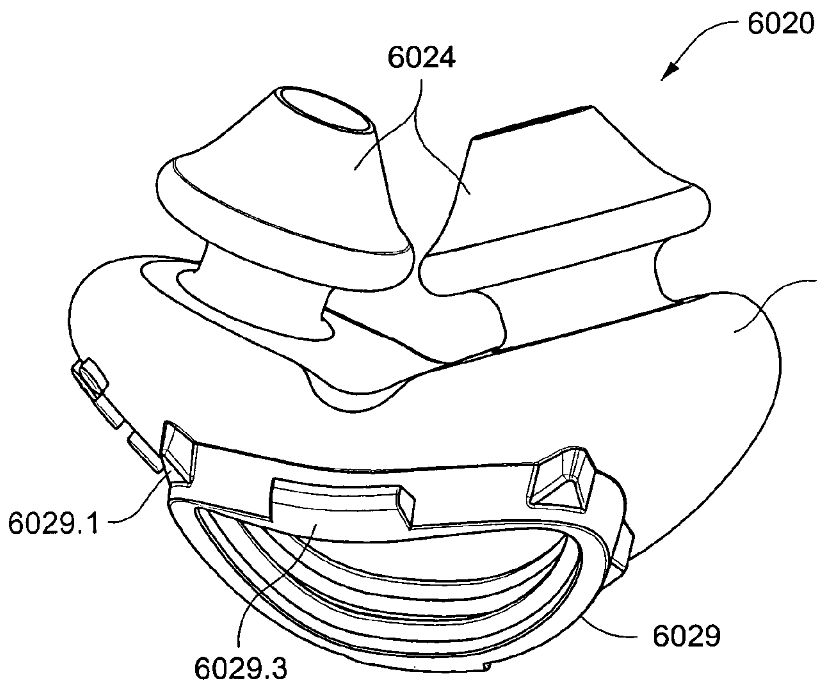
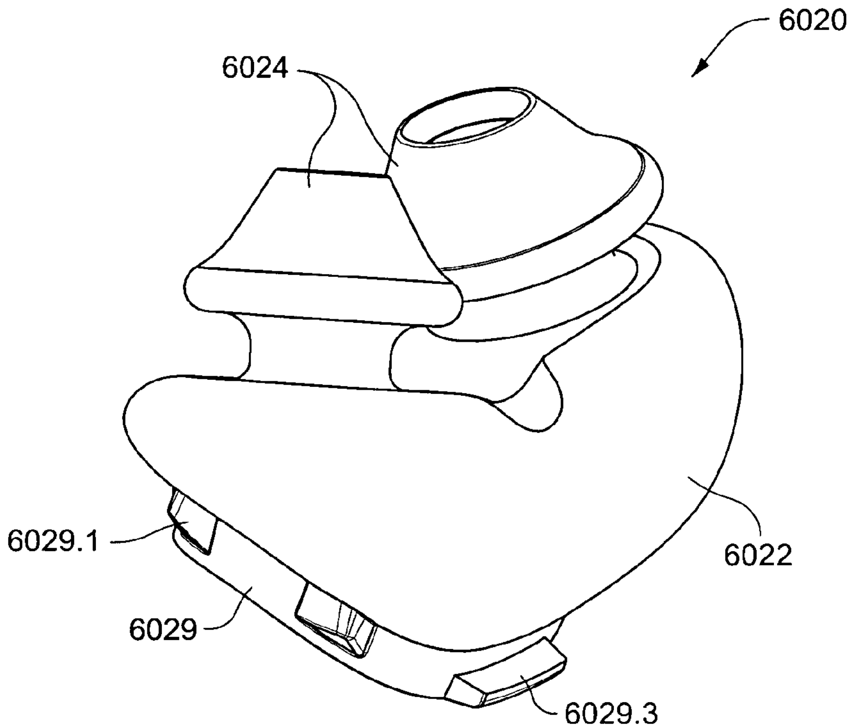


Fig. 16-15-1



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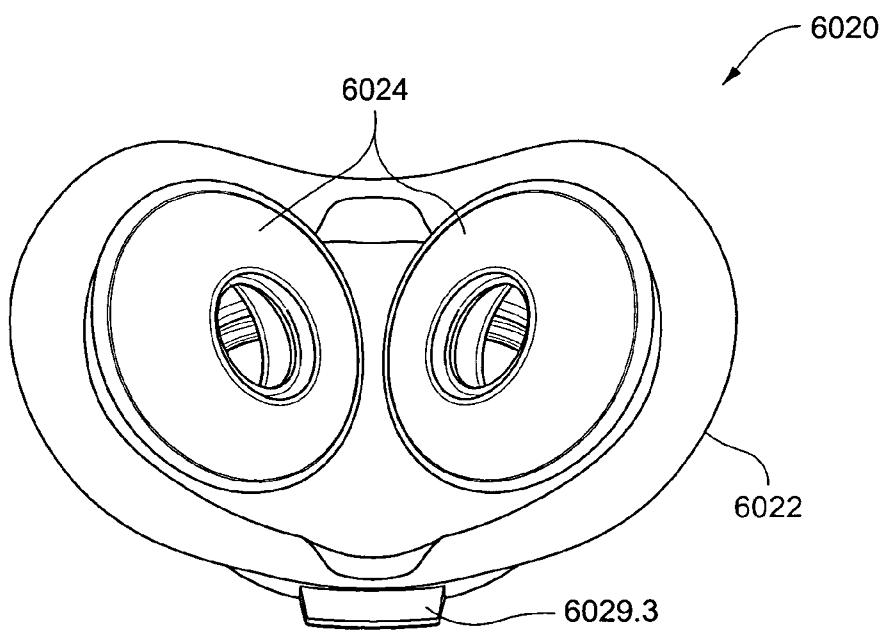

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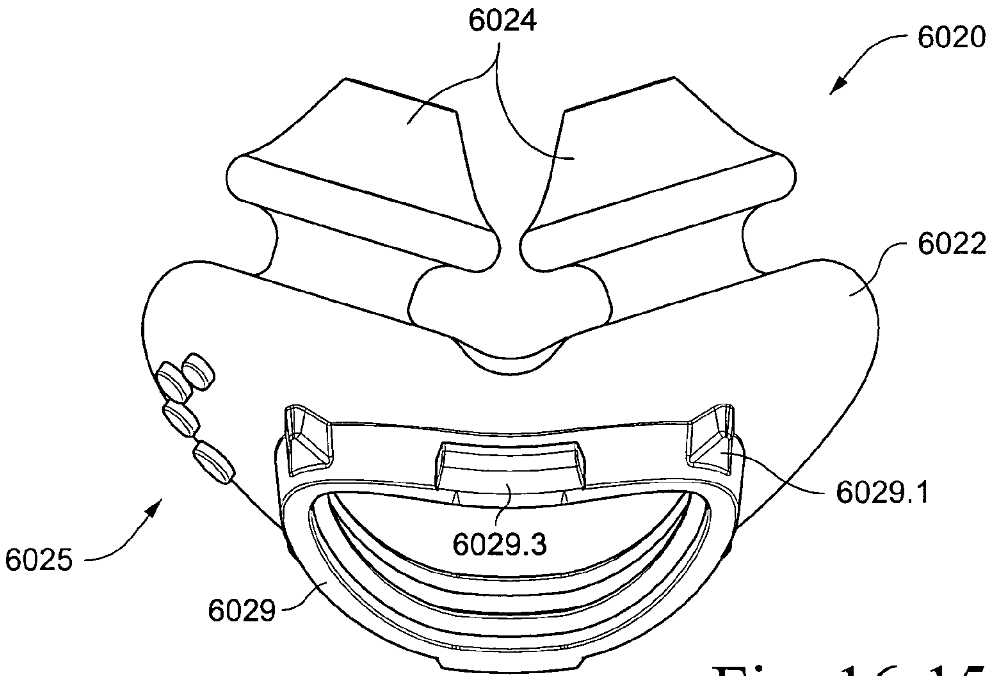

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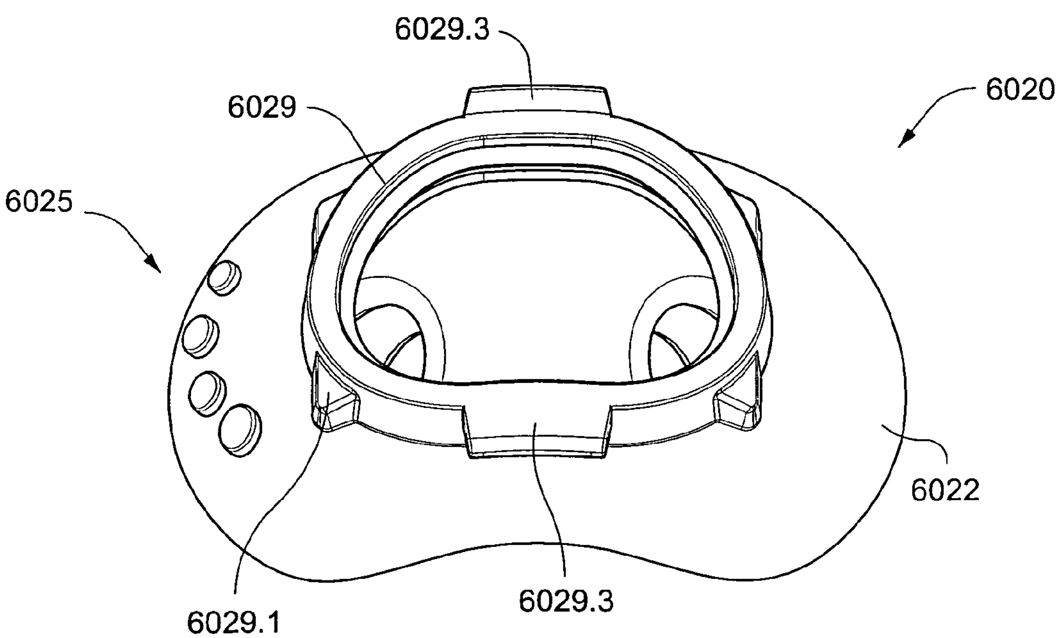

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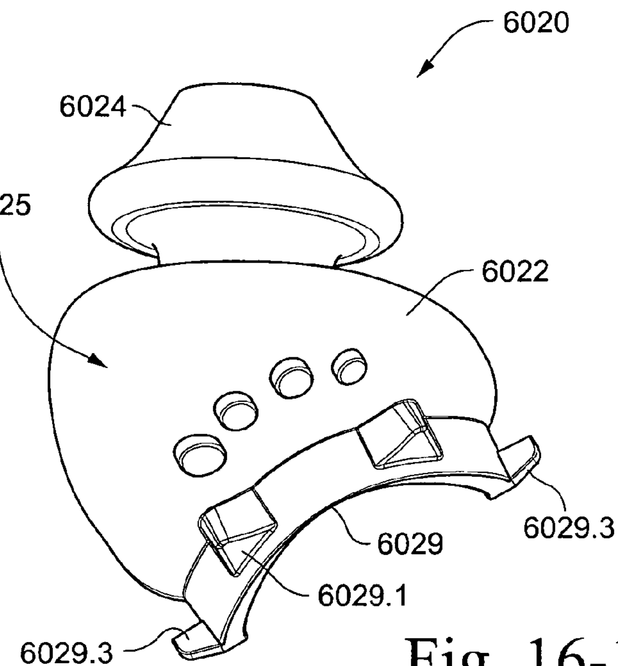

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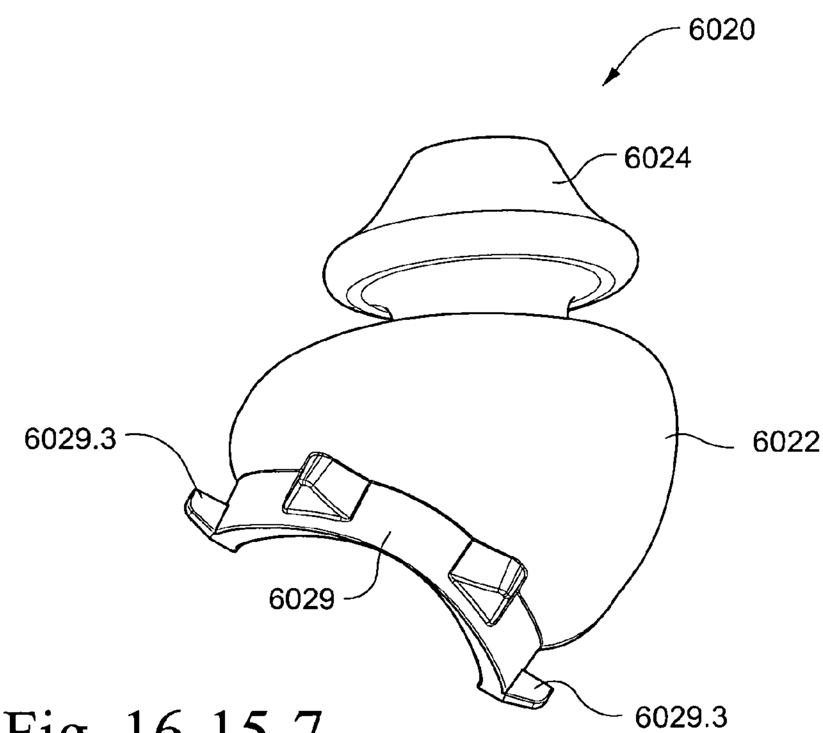

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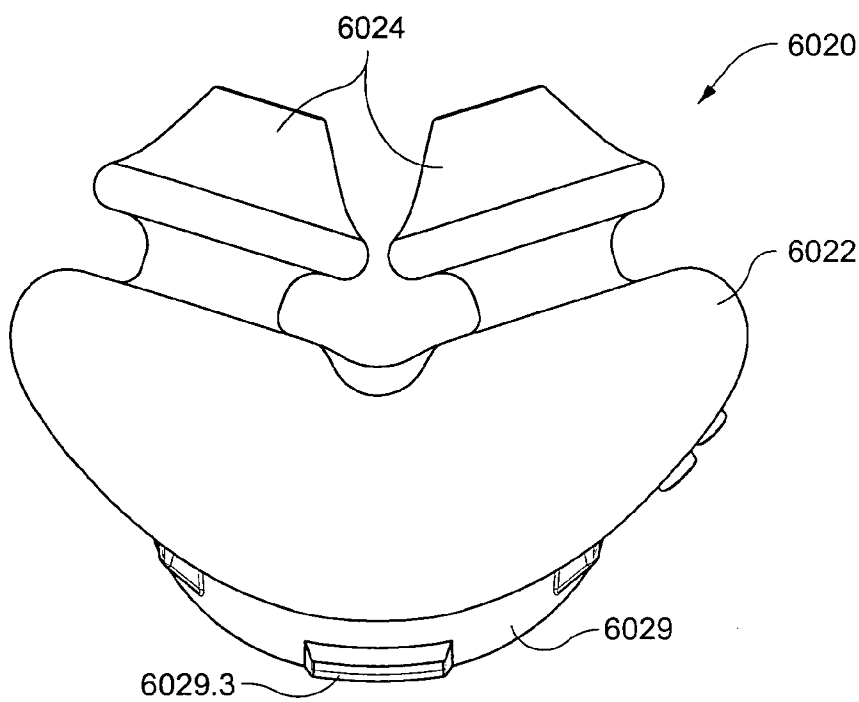

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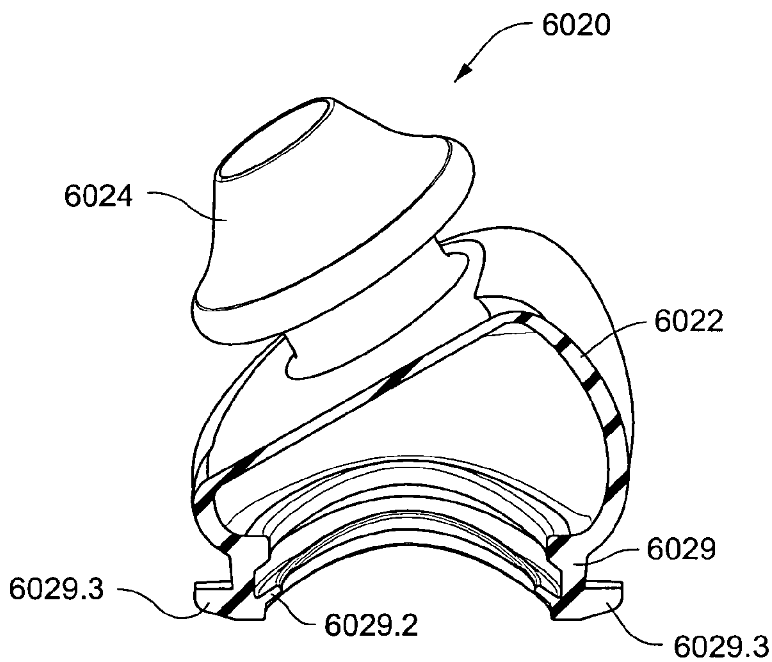

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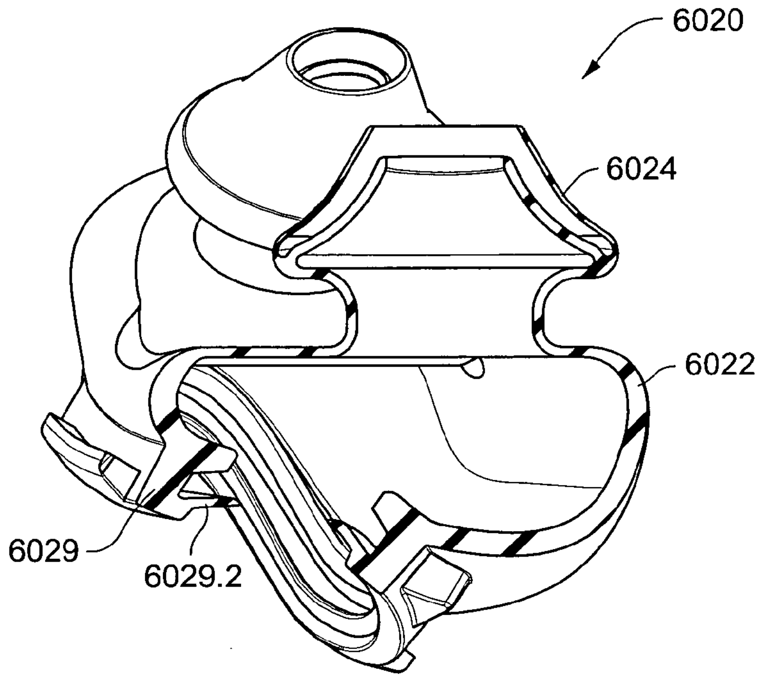

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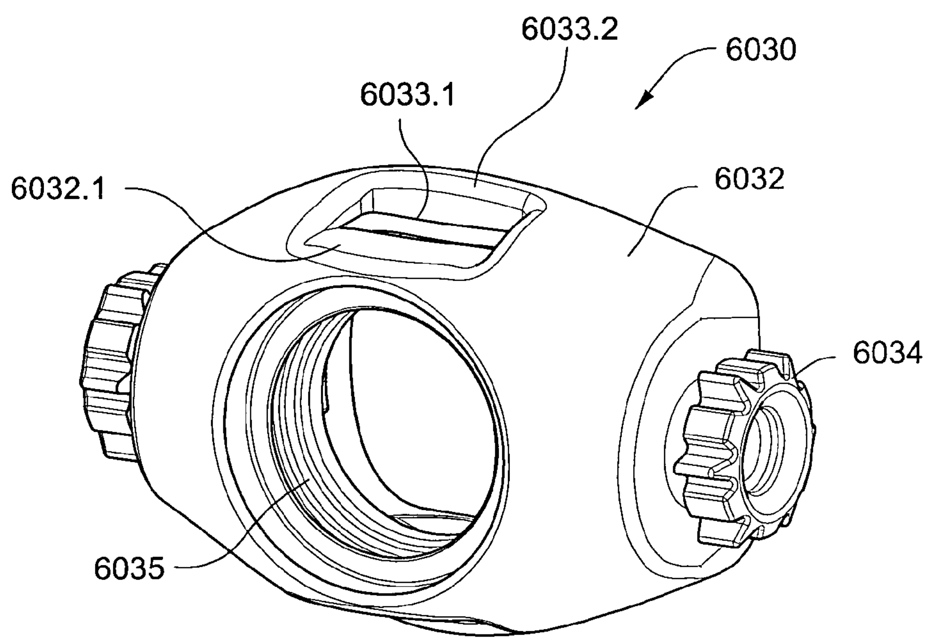

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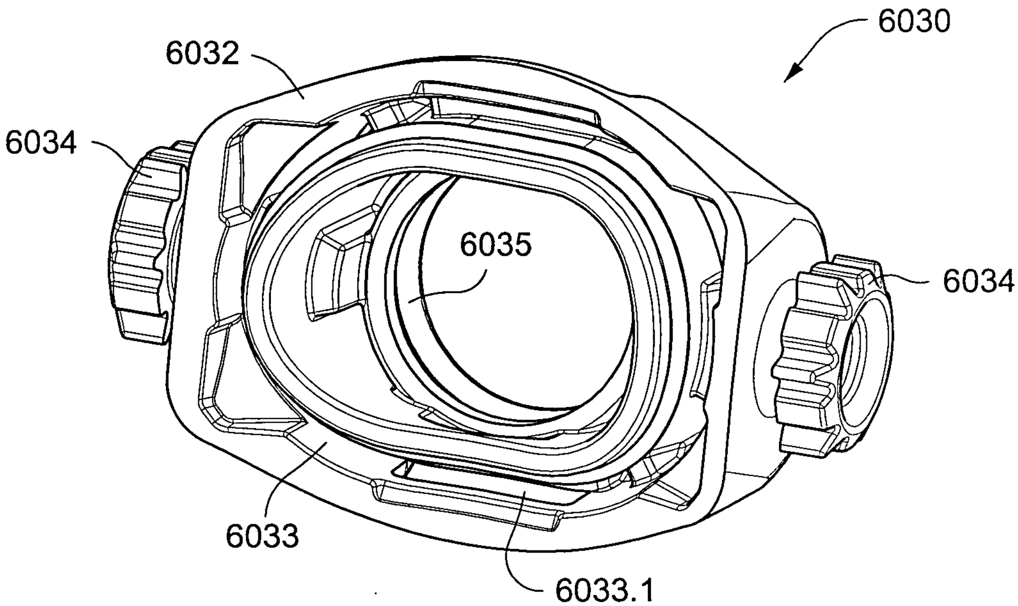

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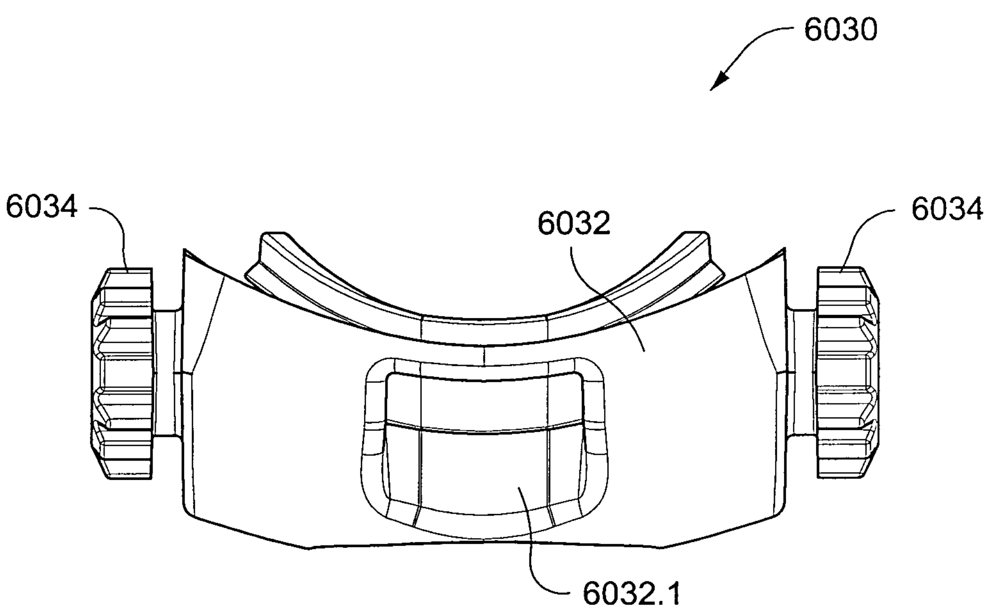

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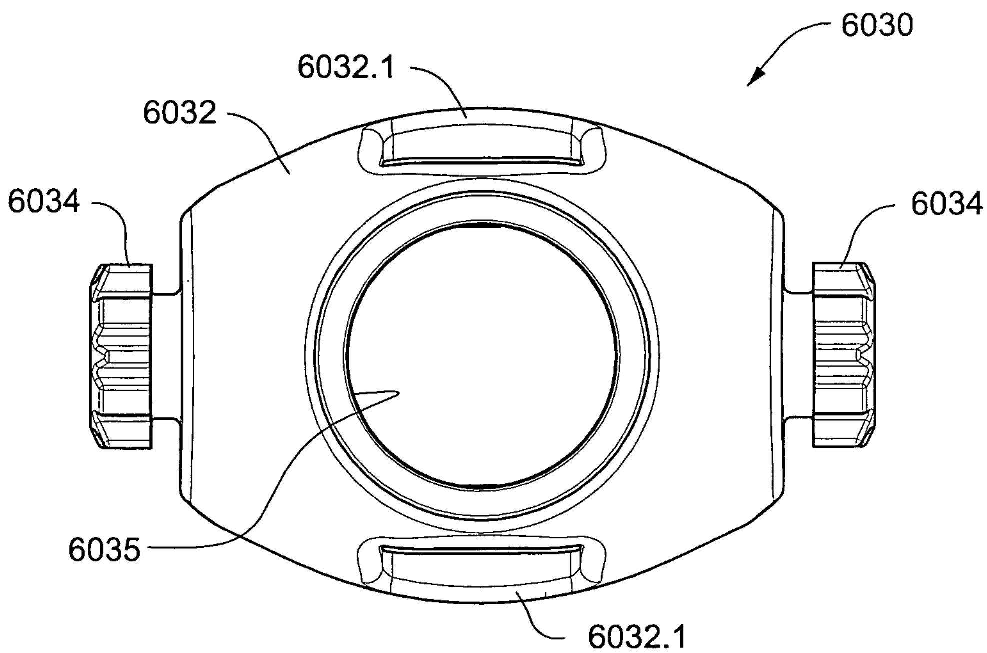

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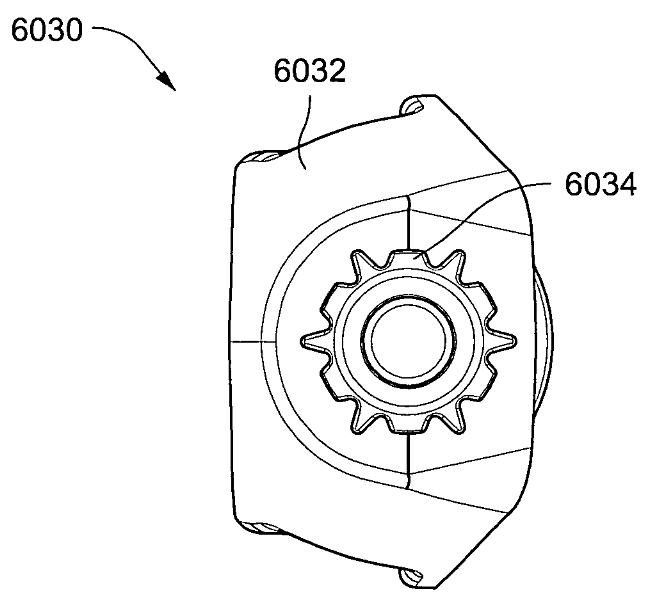

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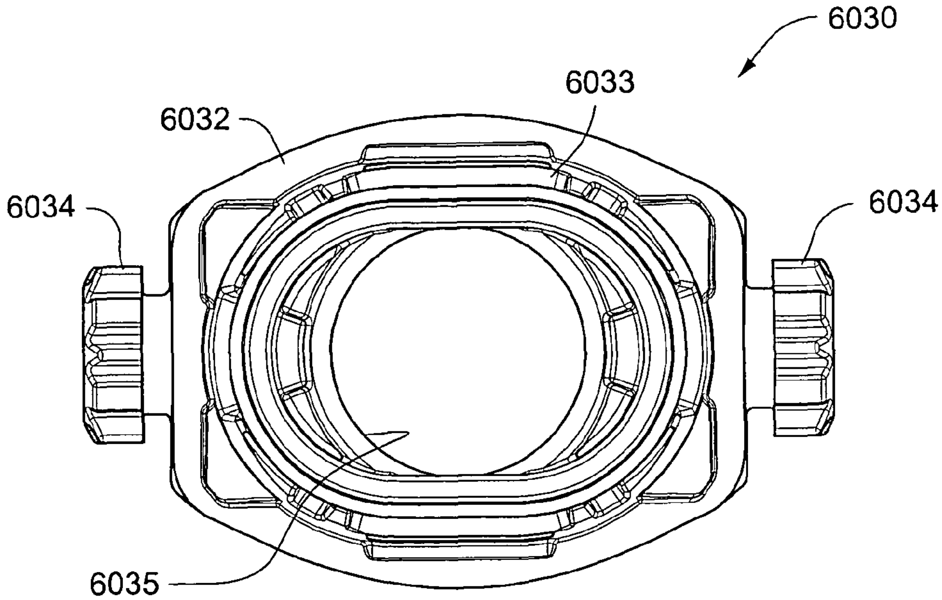

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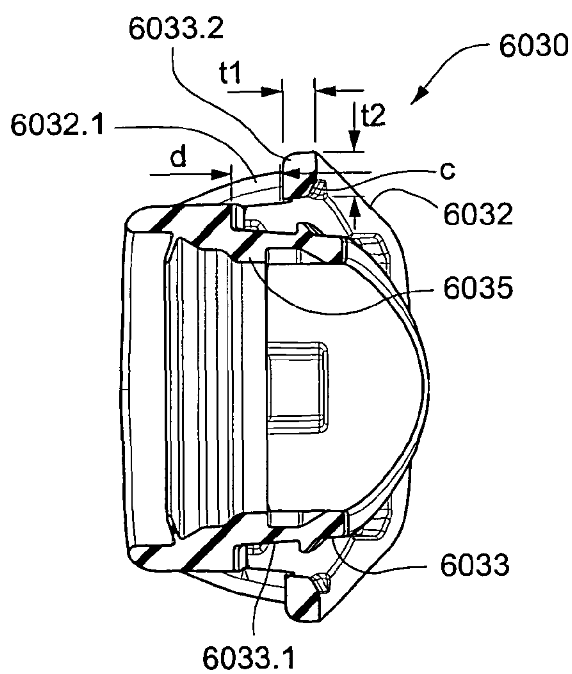

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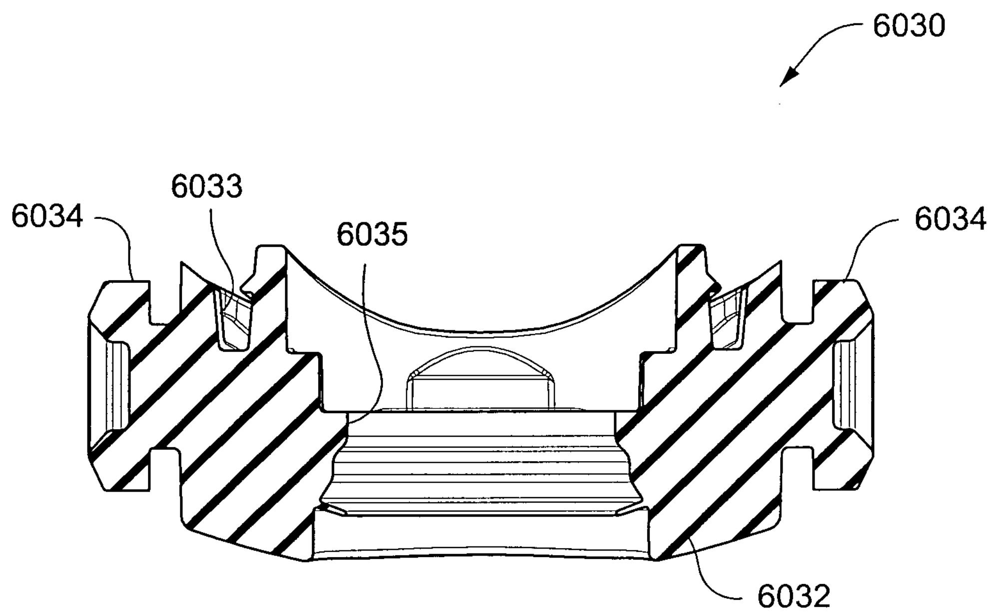

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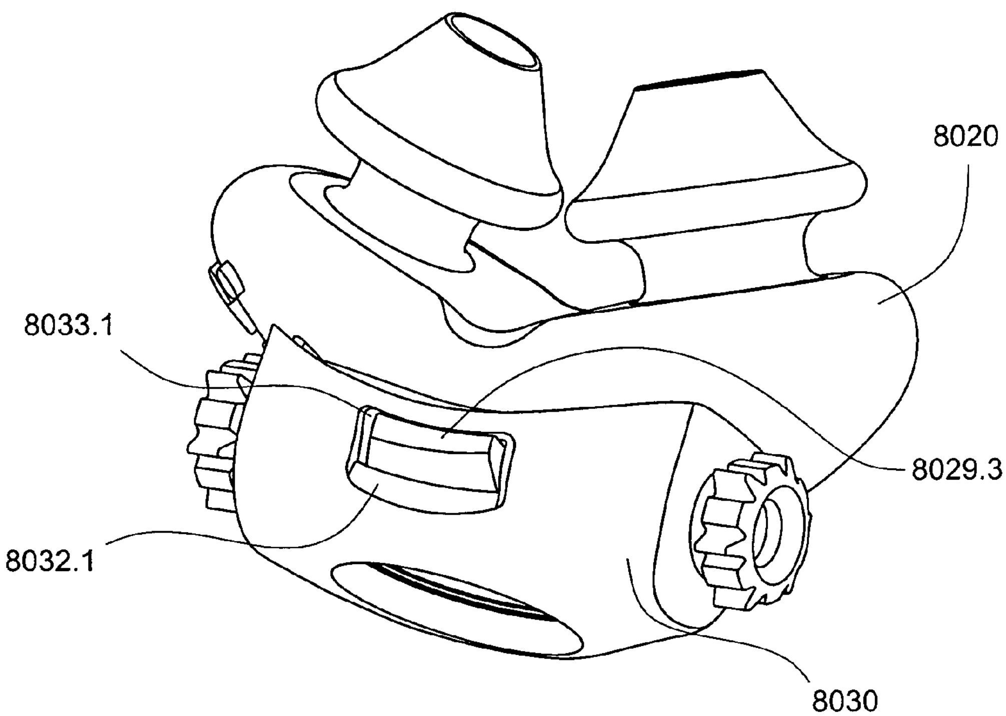


Fig. 16-17

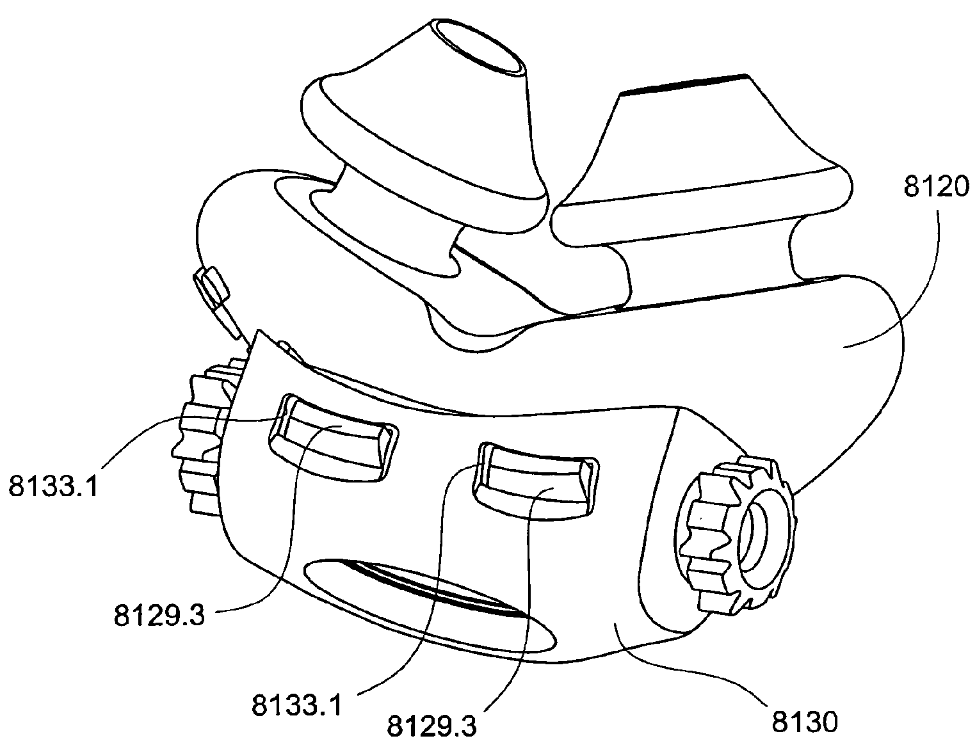
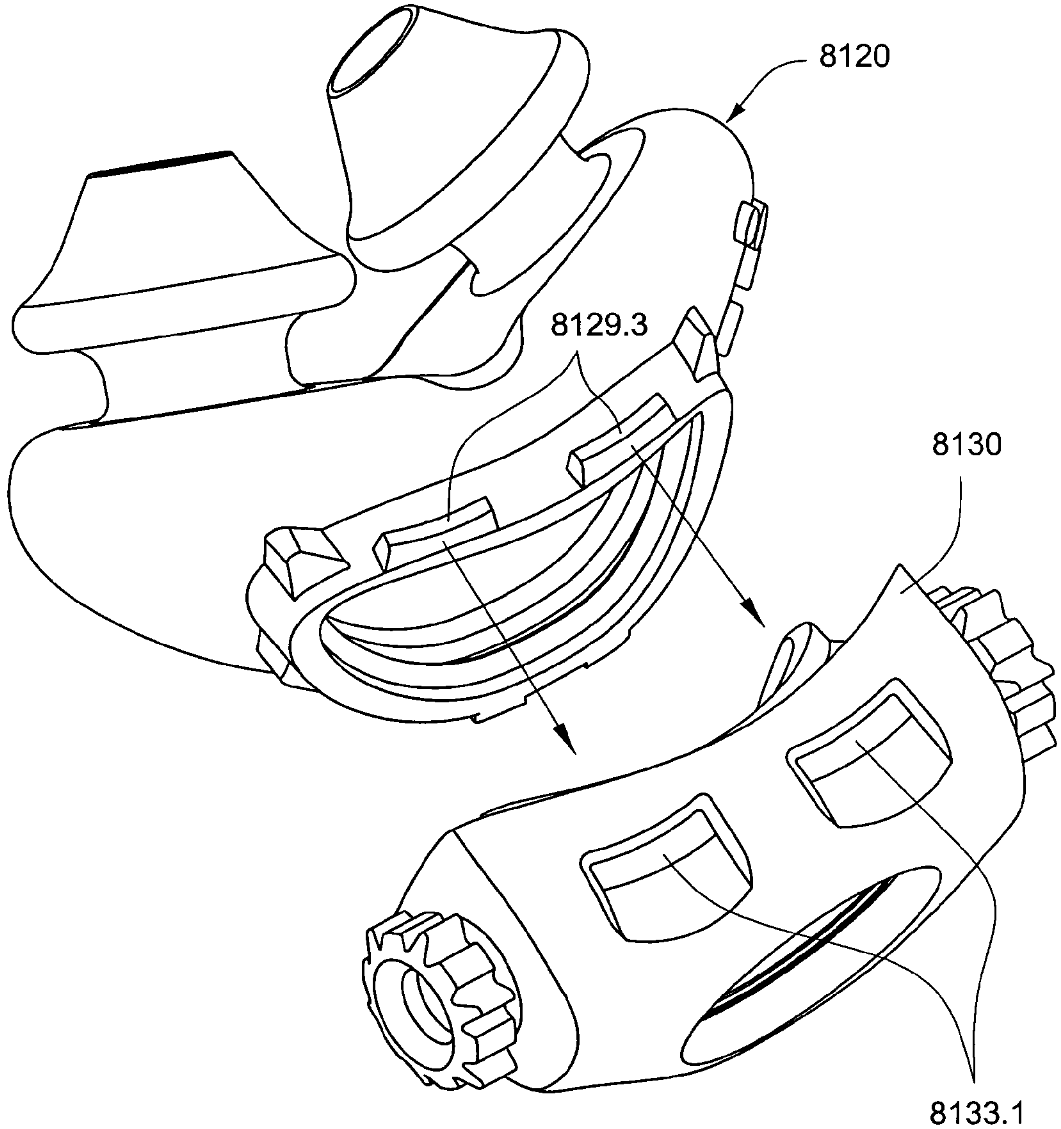


Fig. 16-18-1



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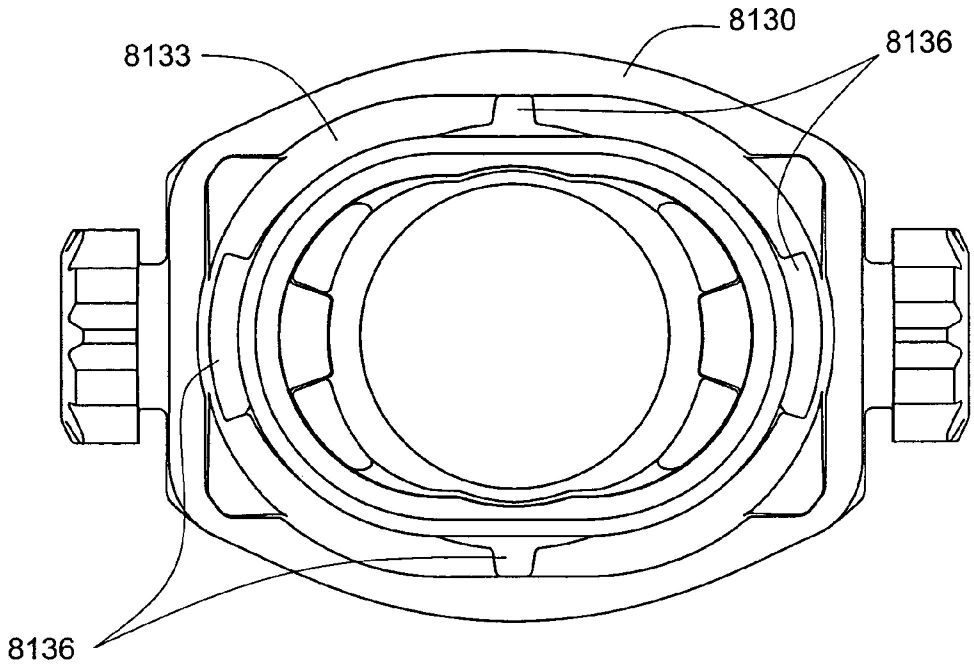

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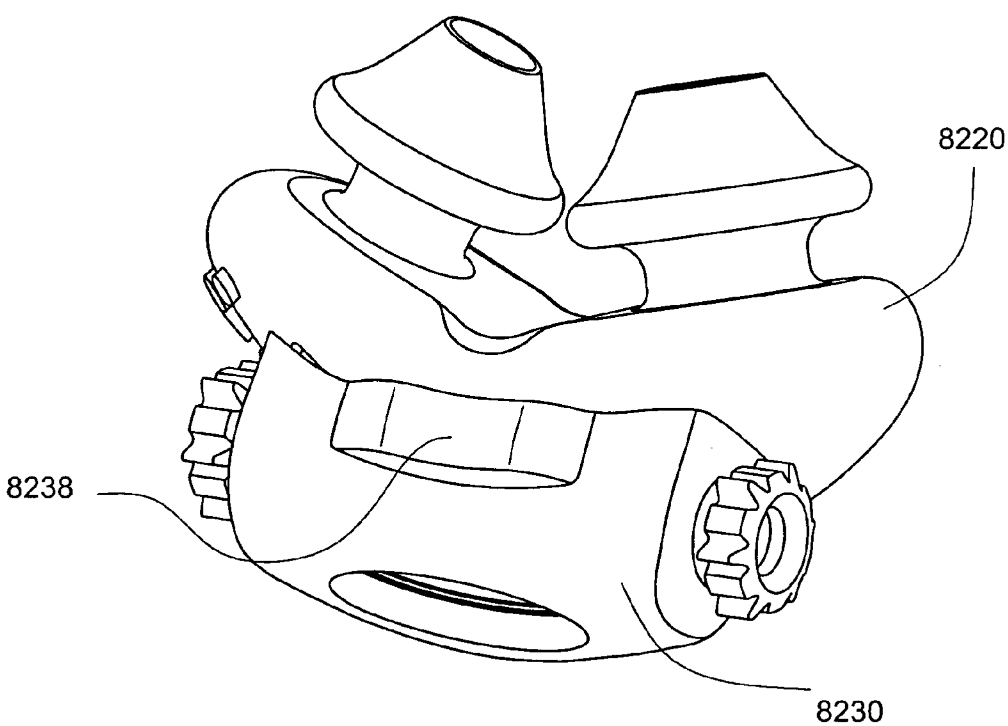

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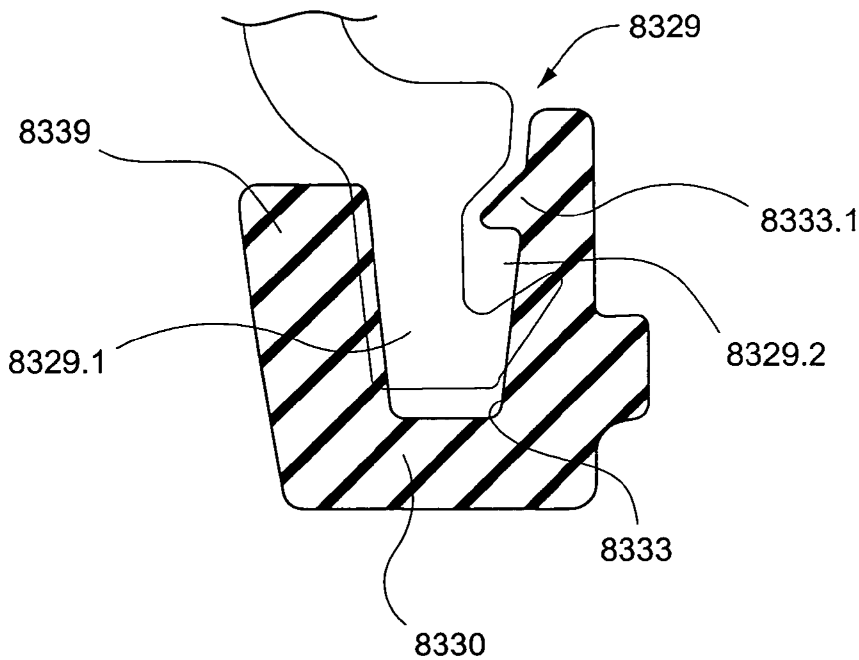

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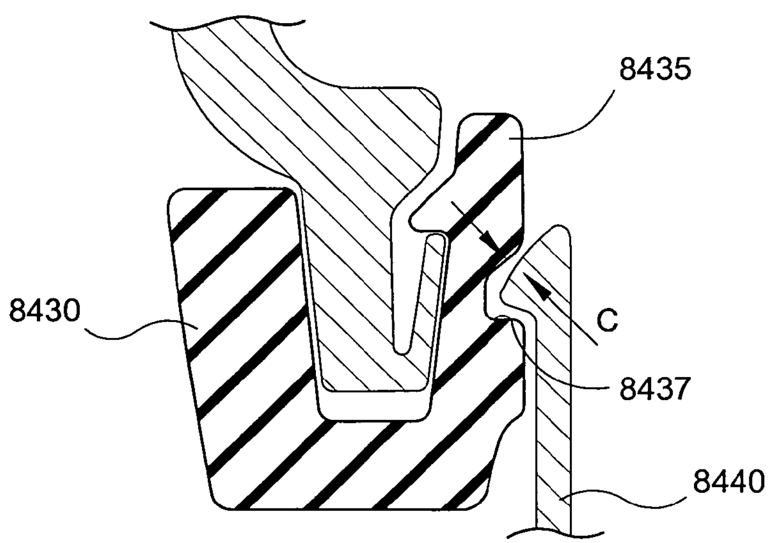

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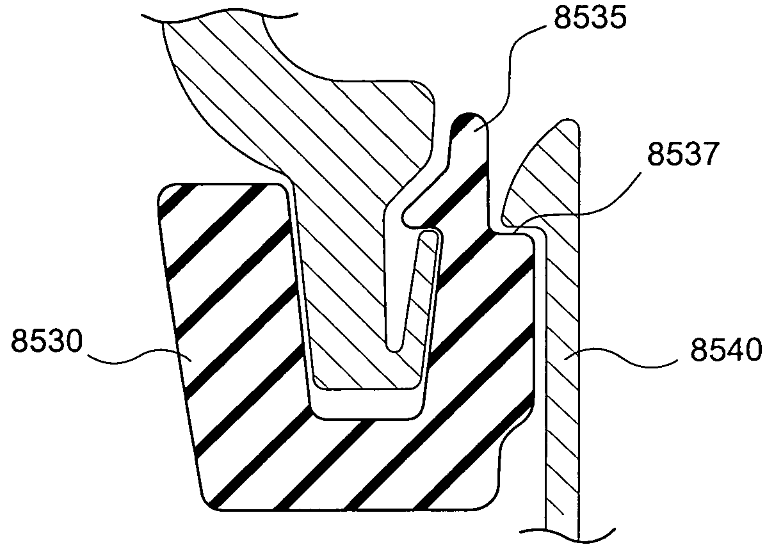

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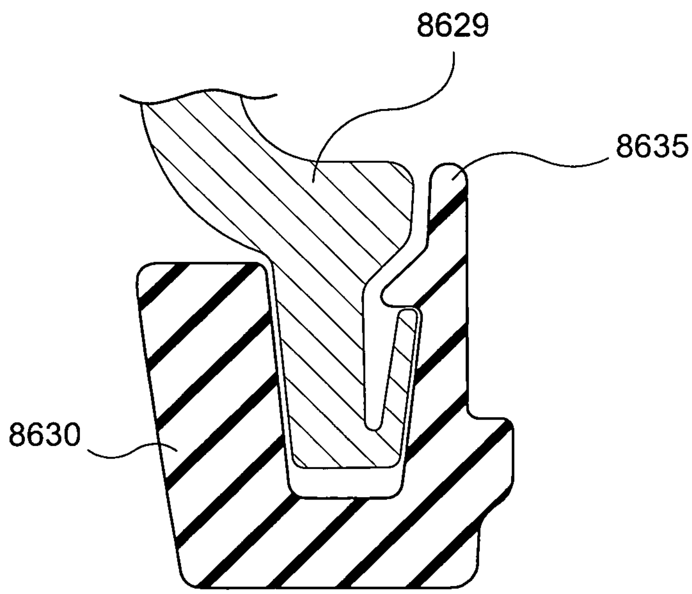

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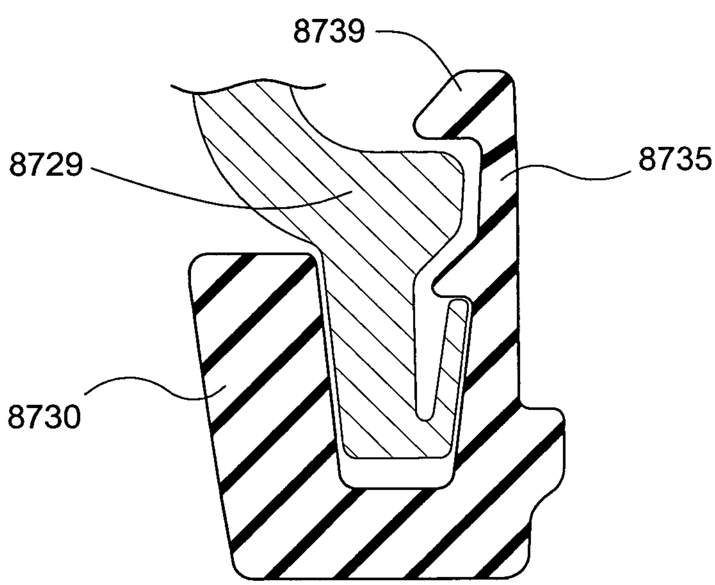
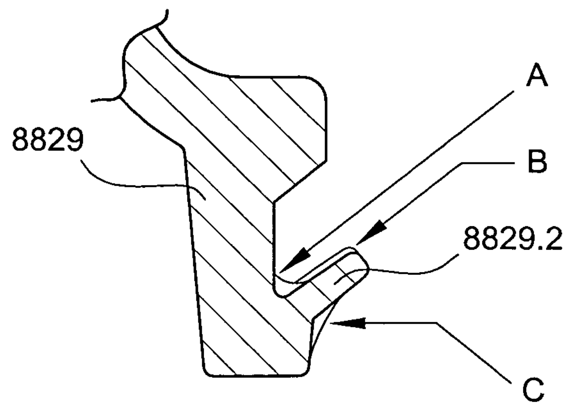


Fig. 16-24



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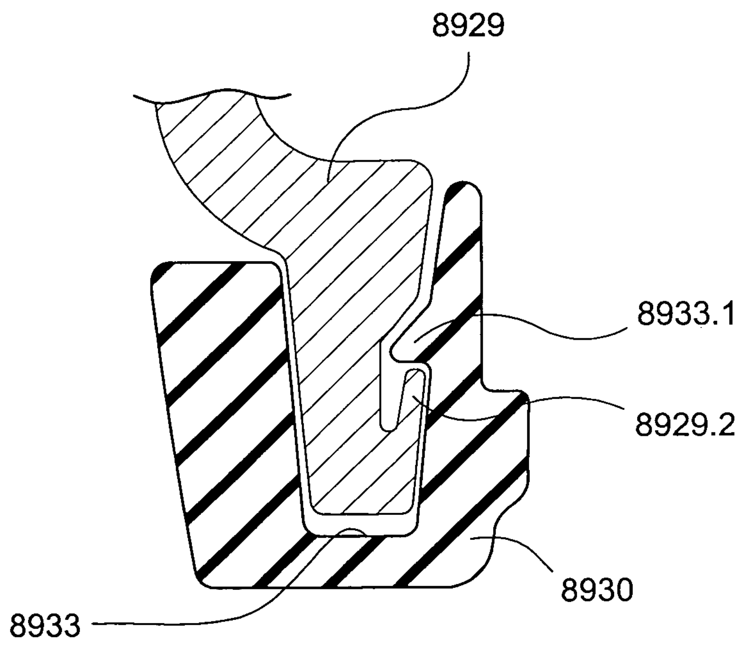

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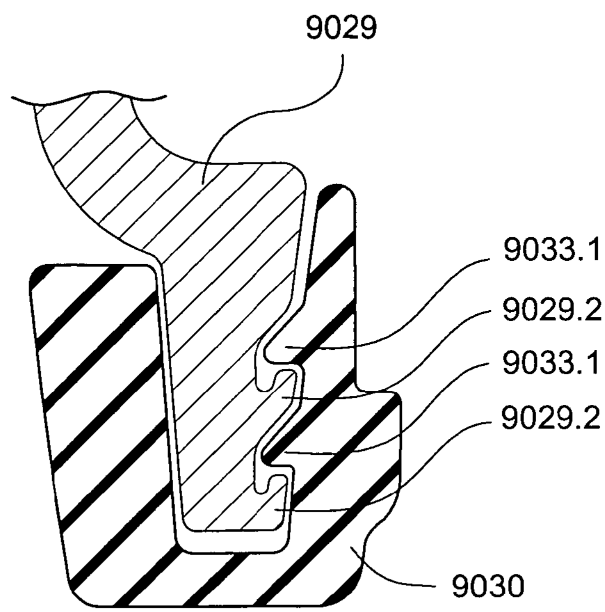

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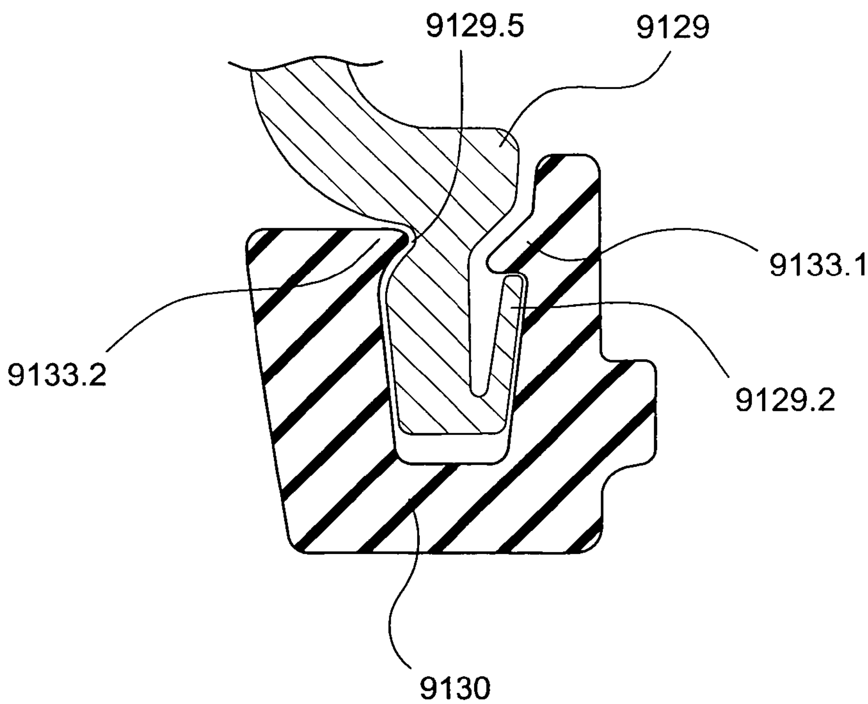

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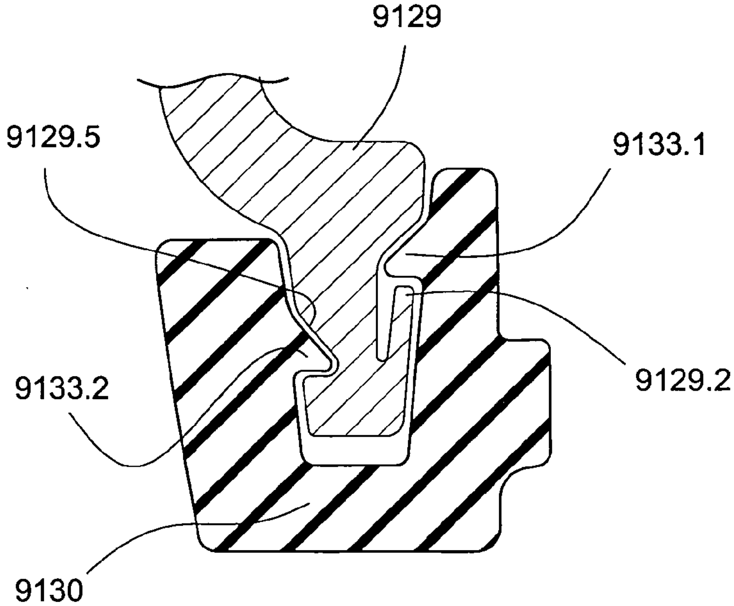

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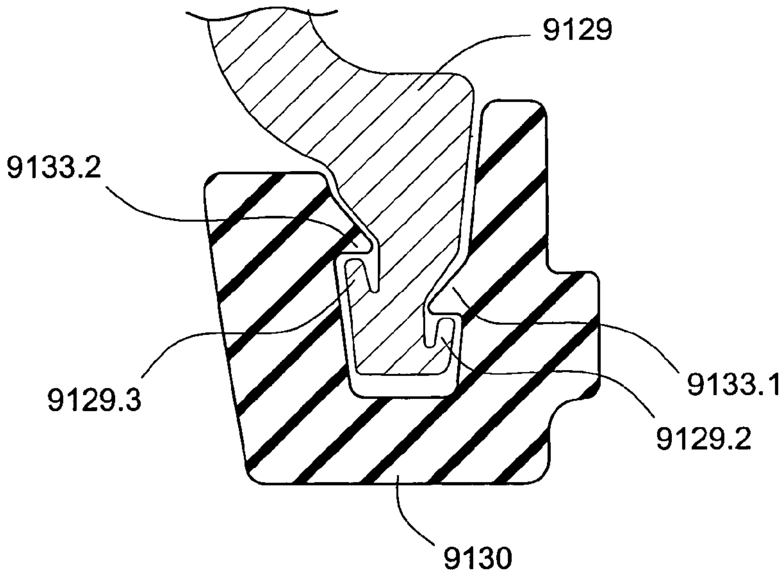

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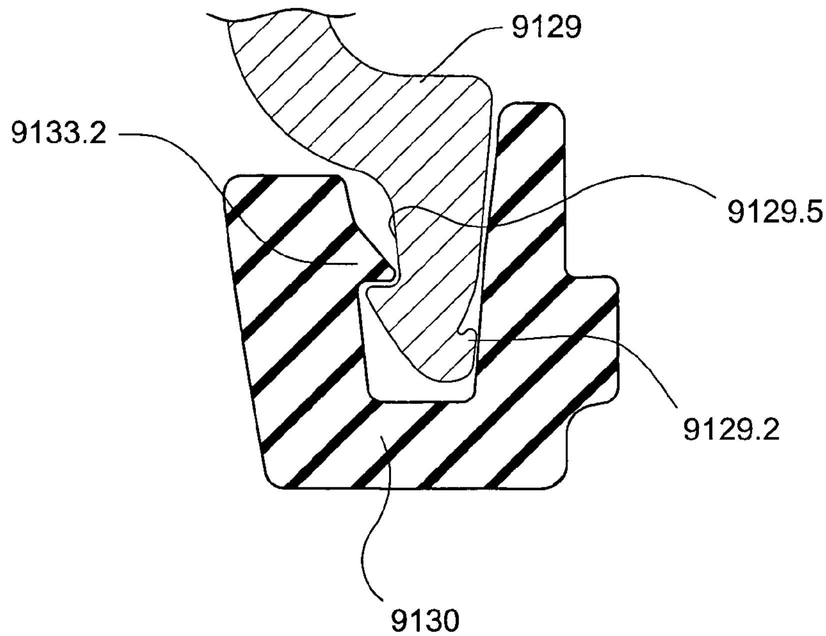

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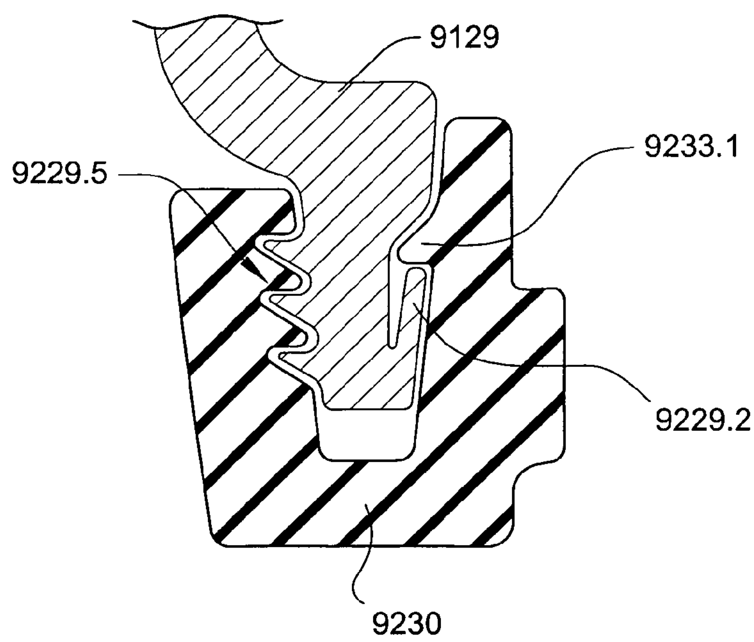

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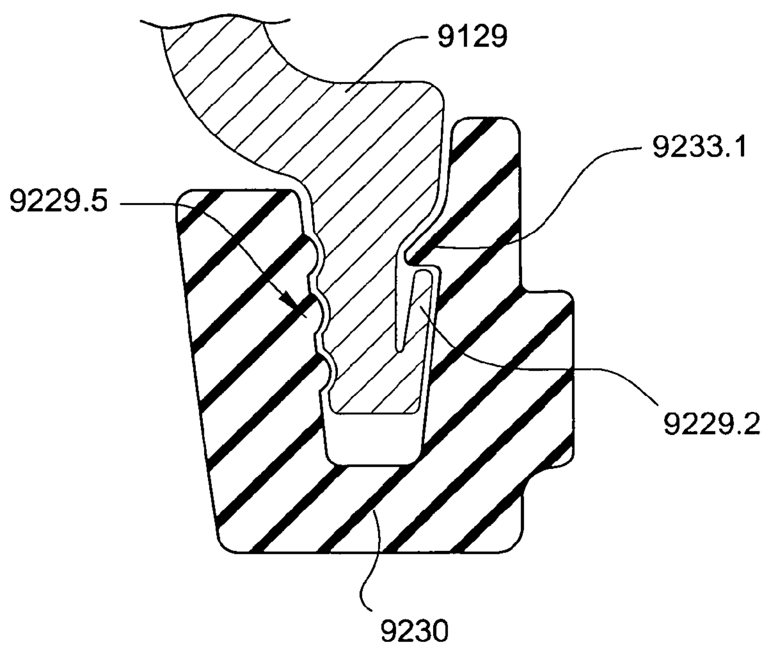

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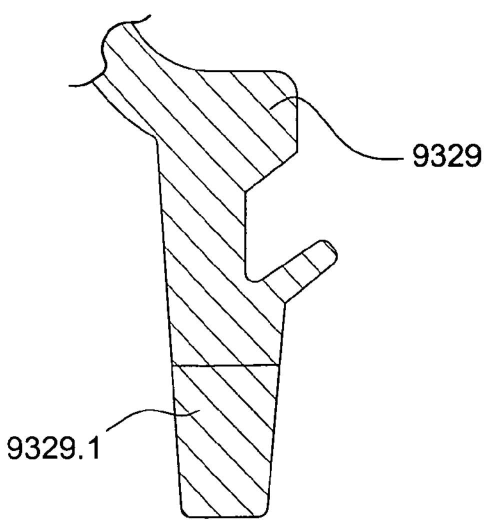

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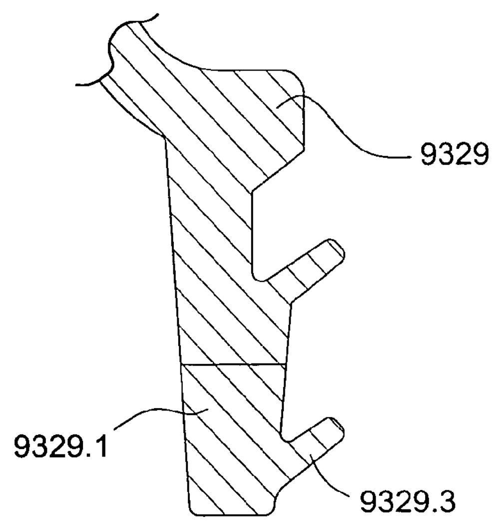
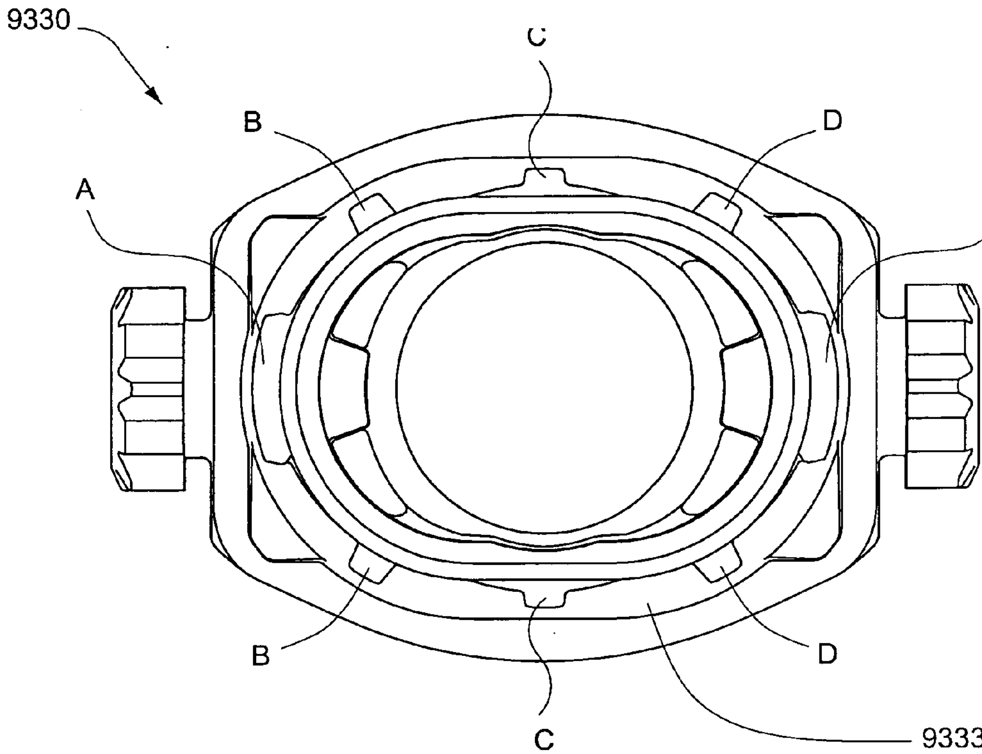


Fig. 16-34-2



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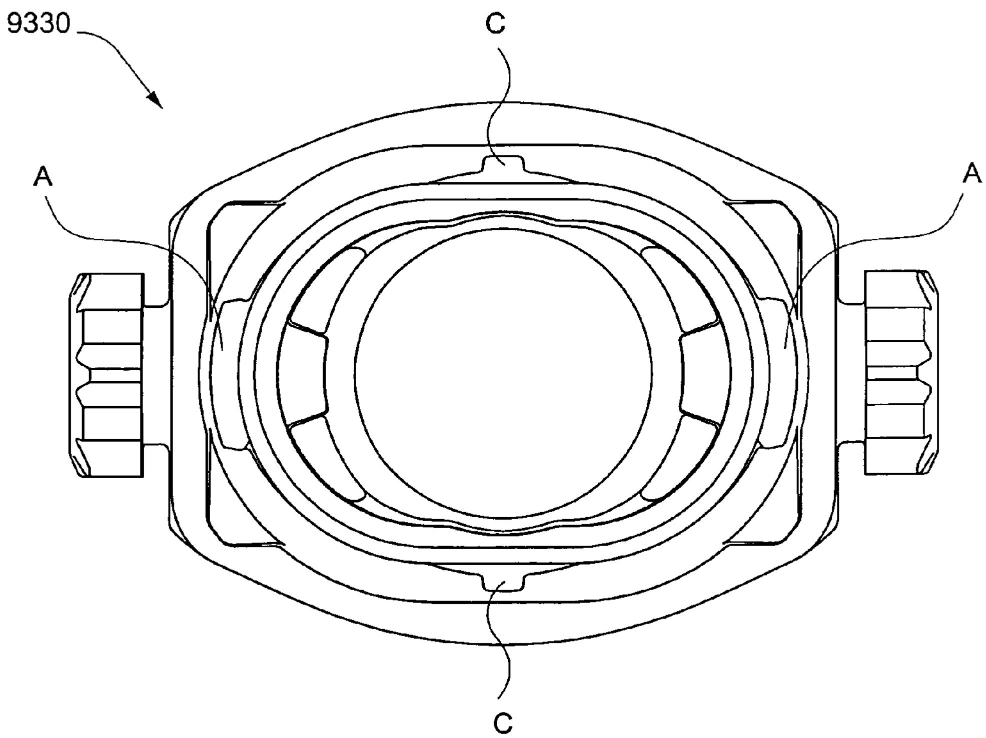
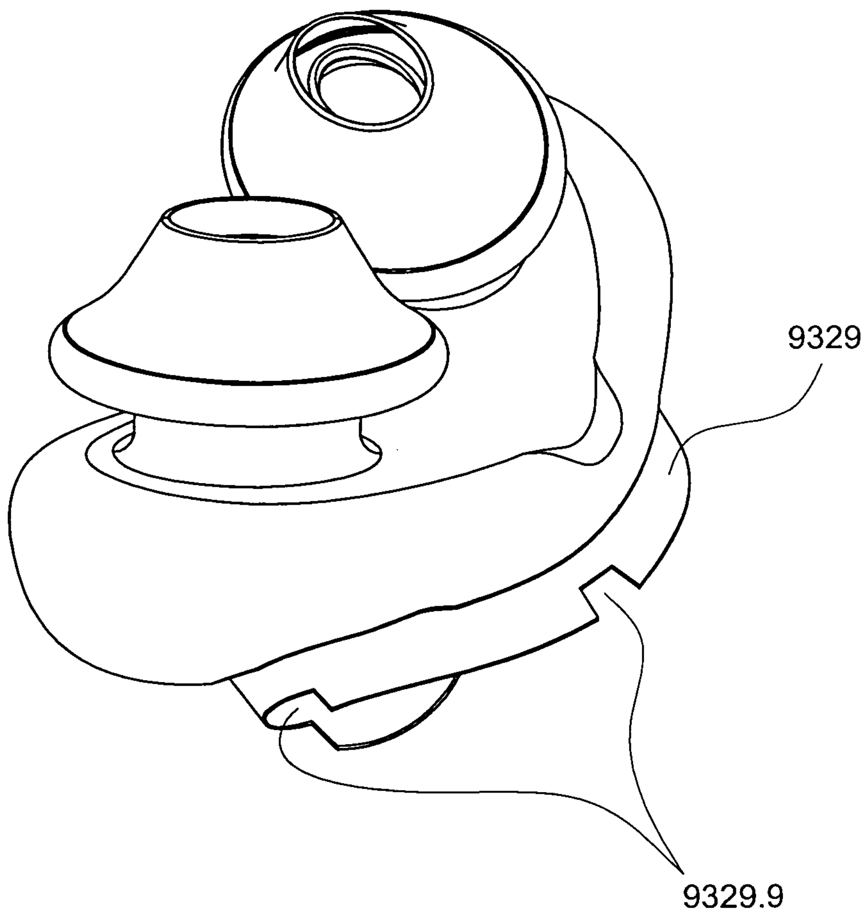


Fig. 16-36



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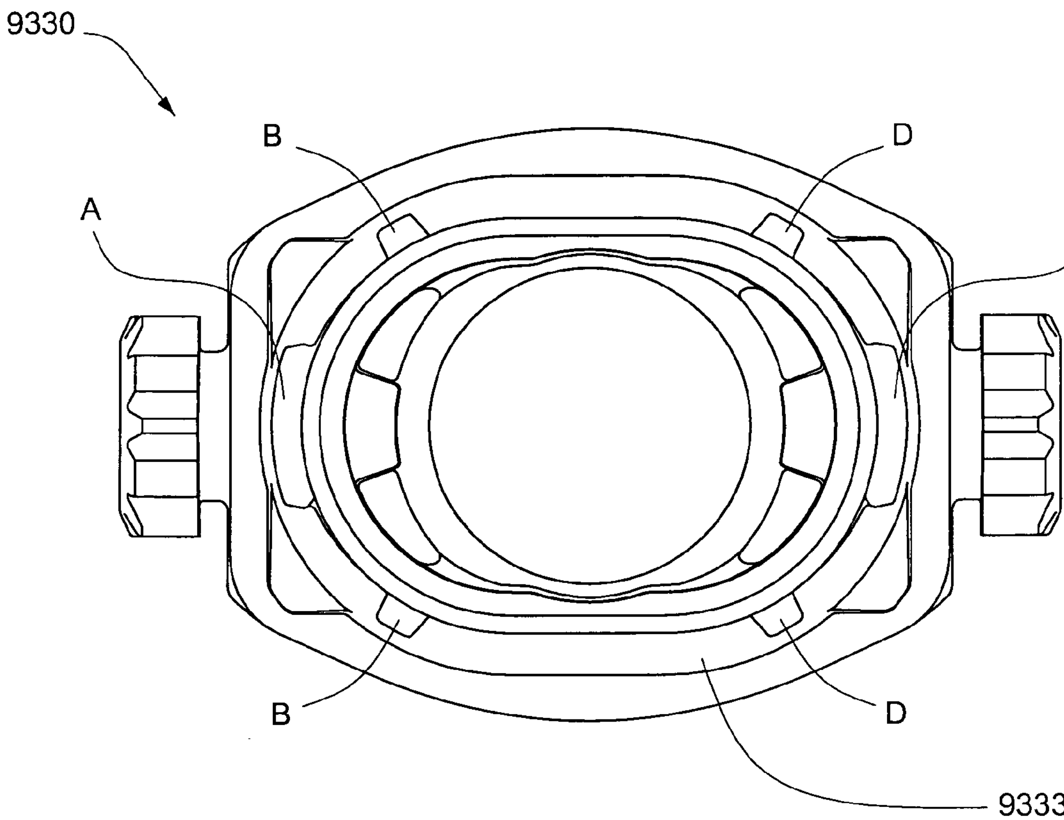
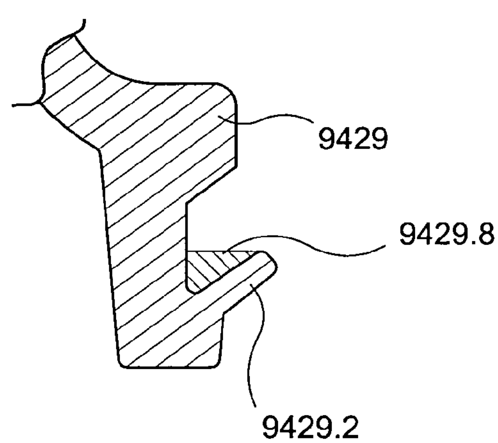


Fig. 16-38



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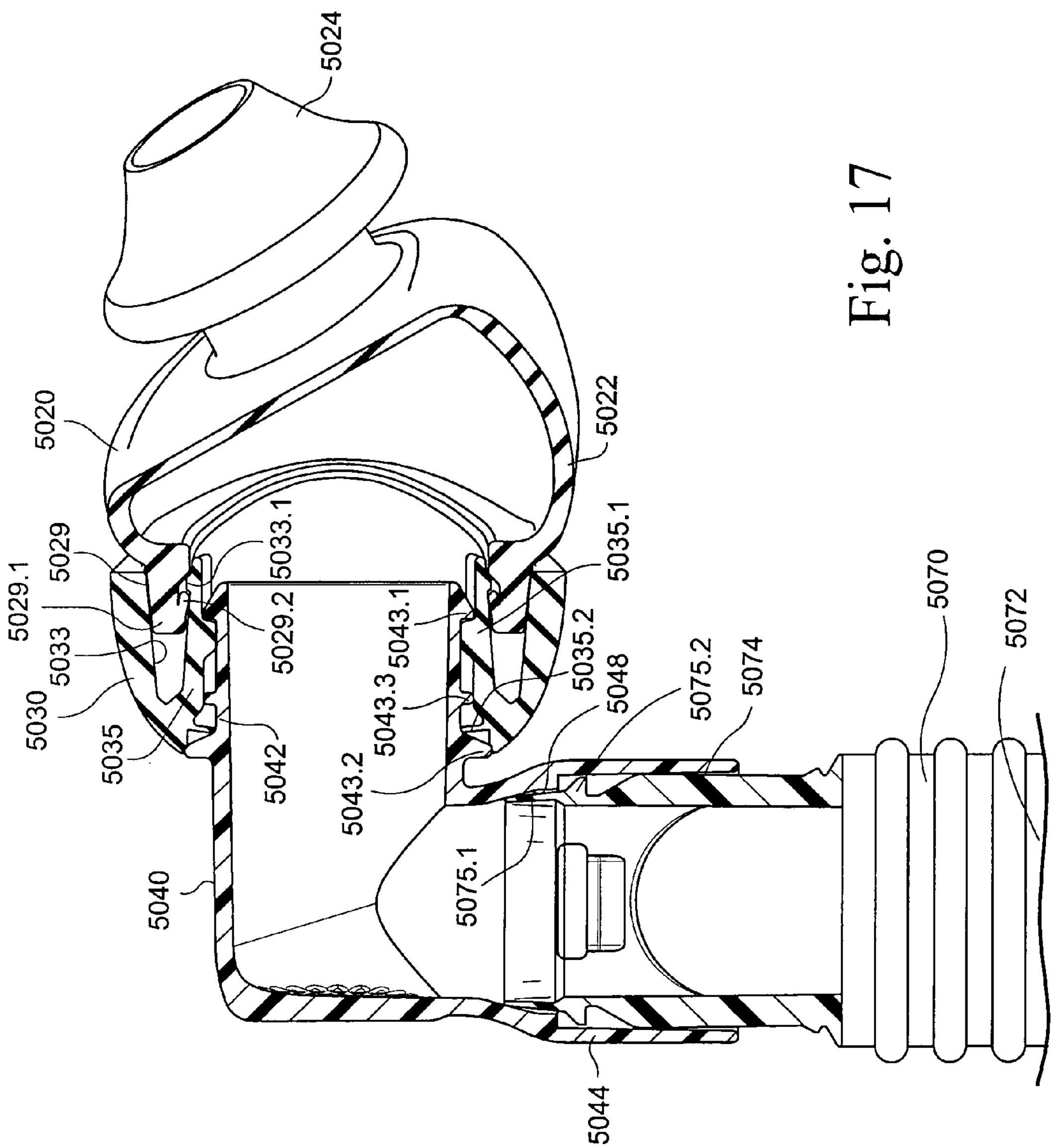
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Fig. 17

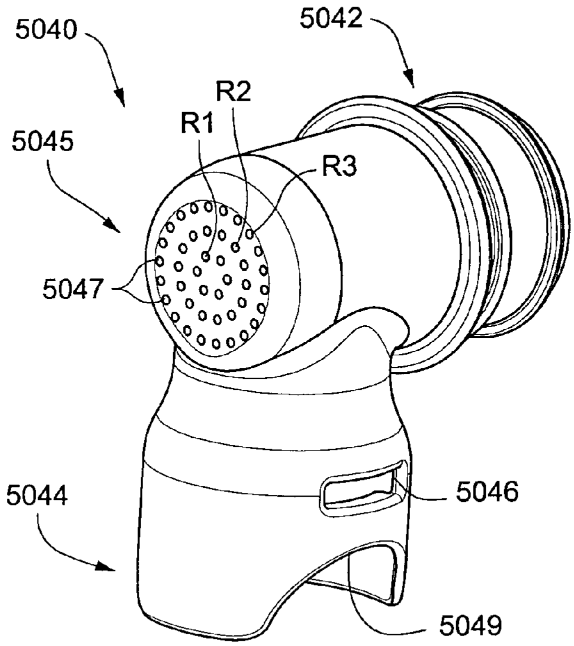


Fig. 18-1

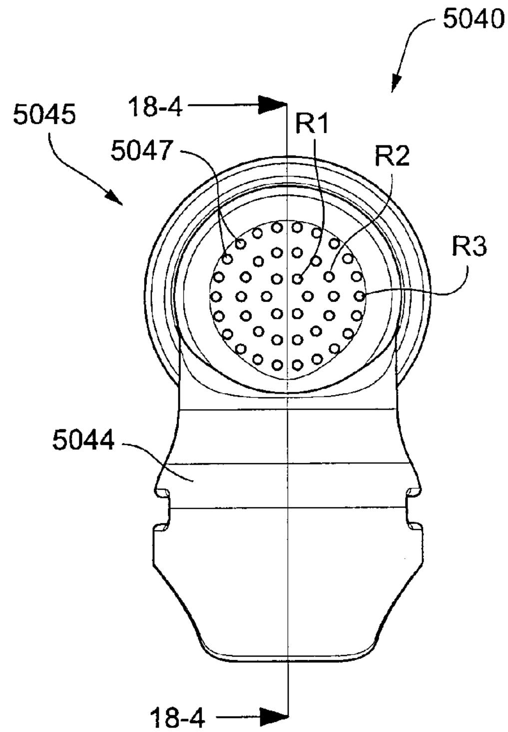
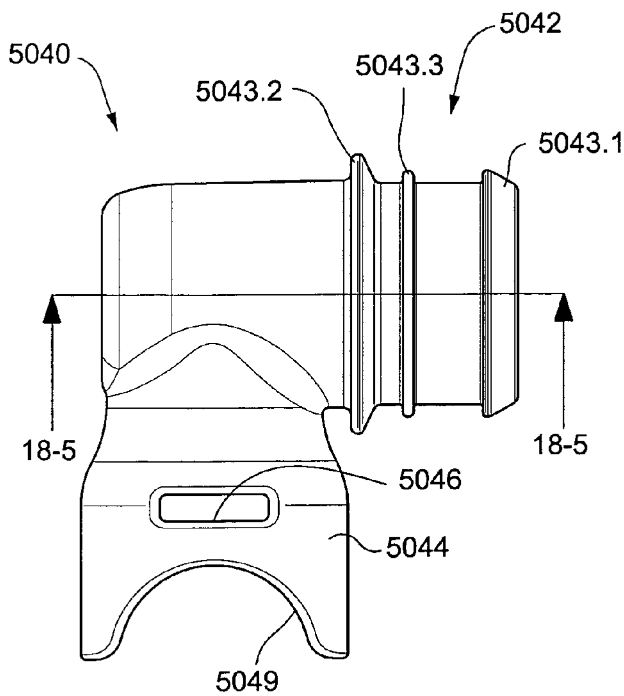


Fig. 18-2



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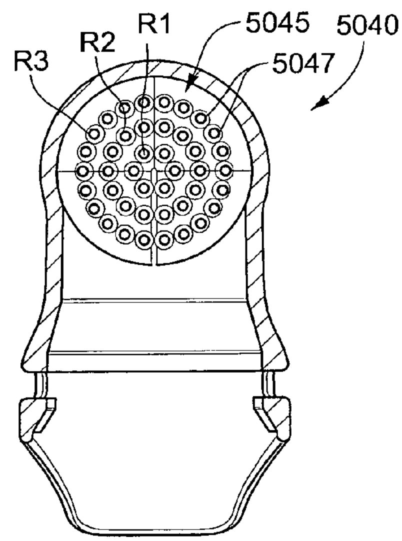
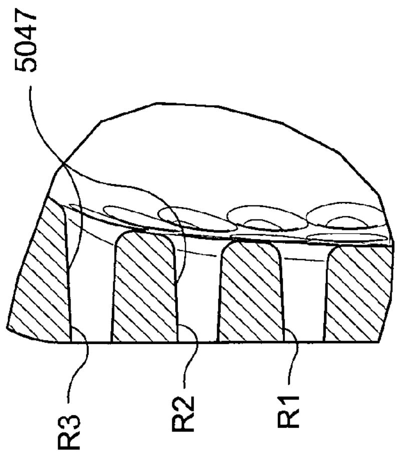


Fig. 18-7



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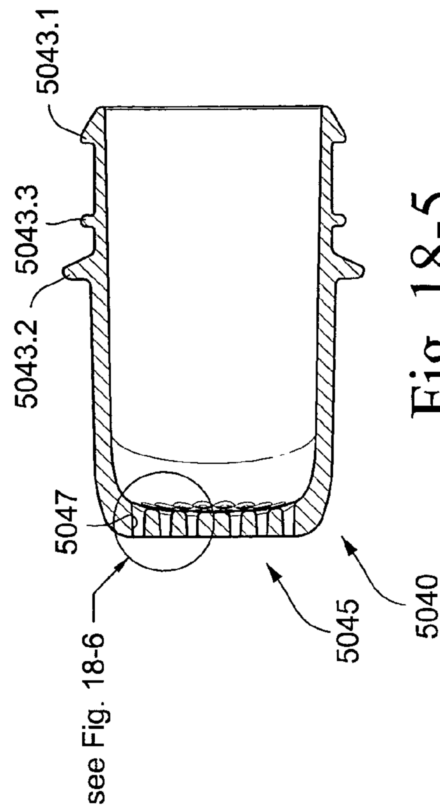

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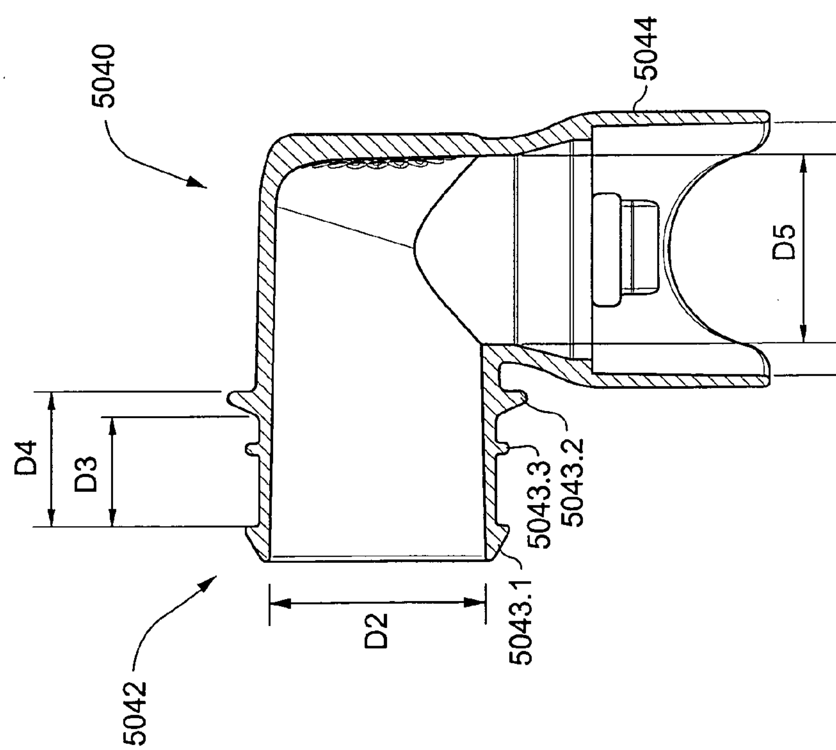
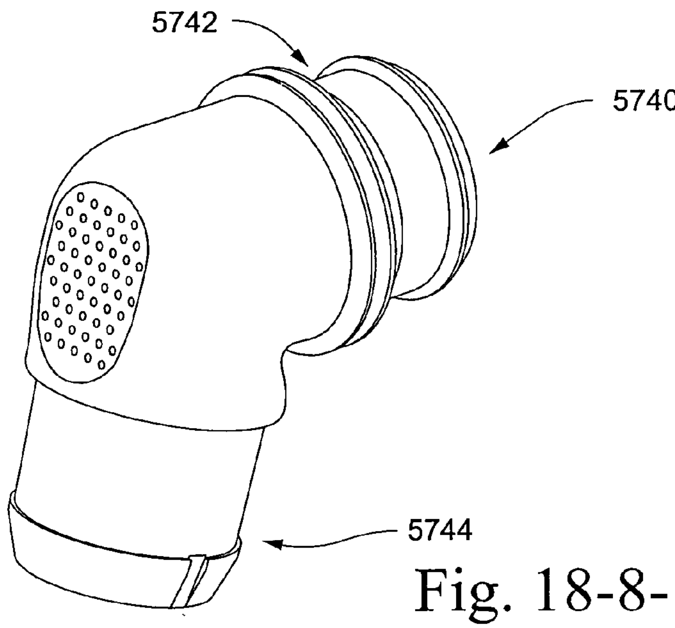


Fig. 18-4



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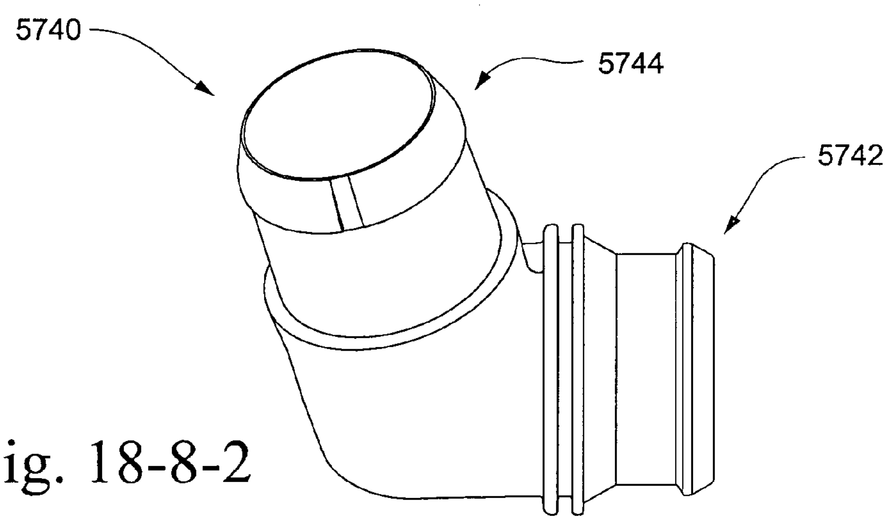

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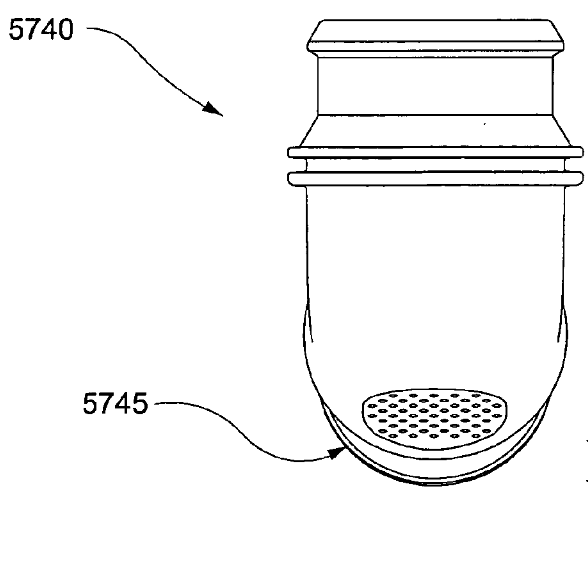

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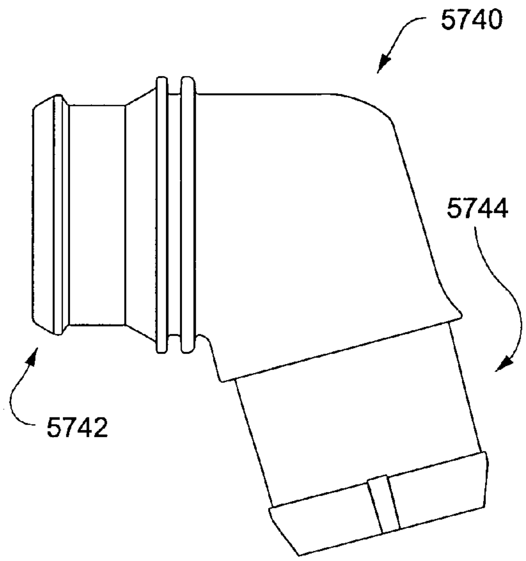

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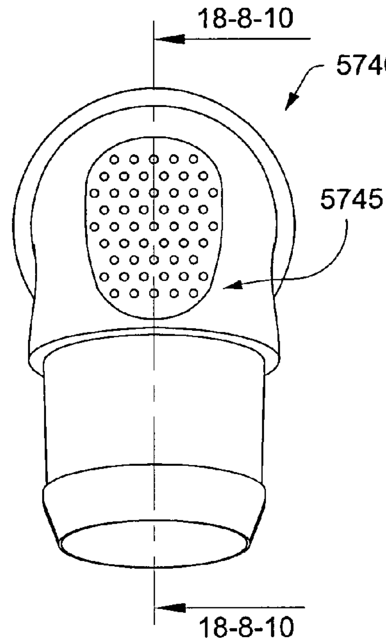

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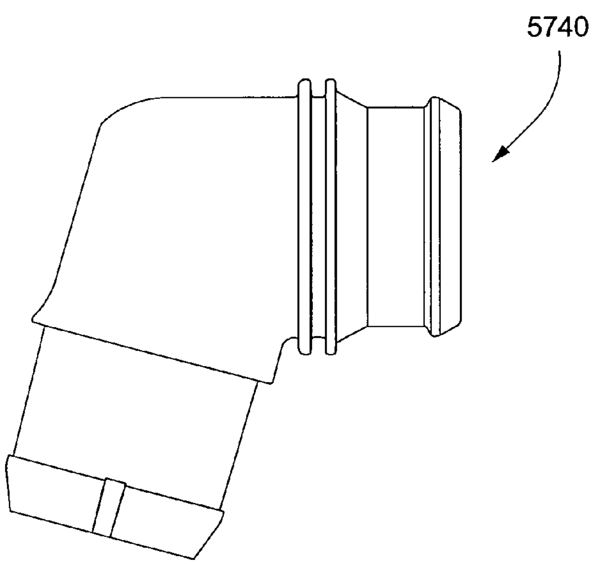

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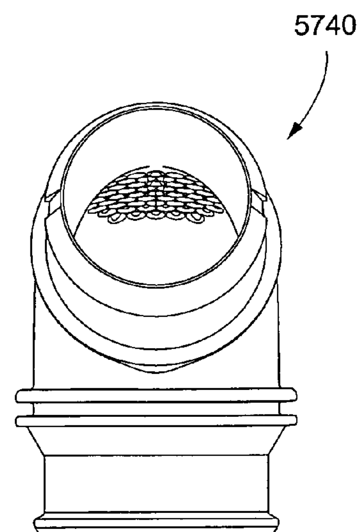

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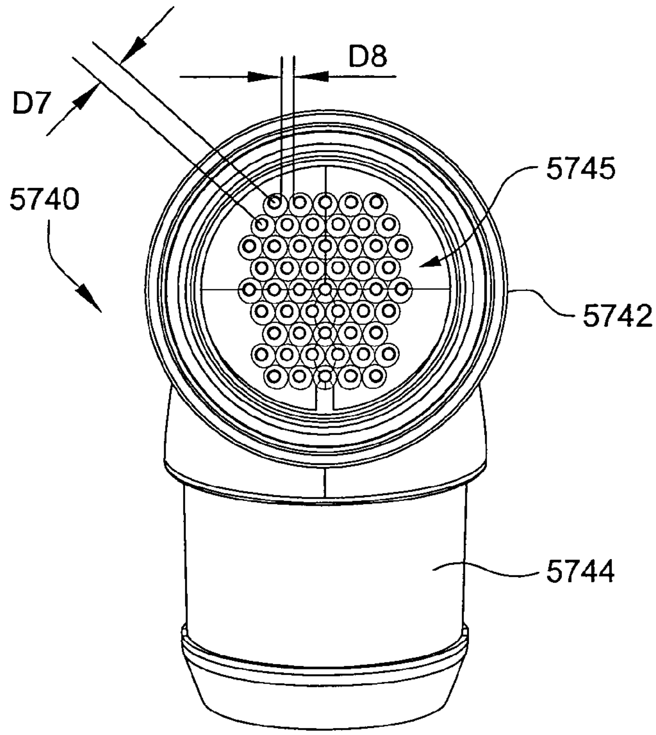

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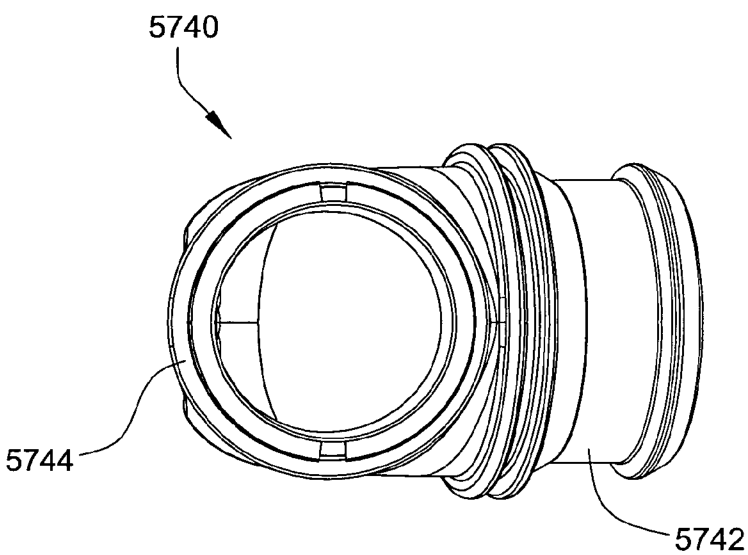

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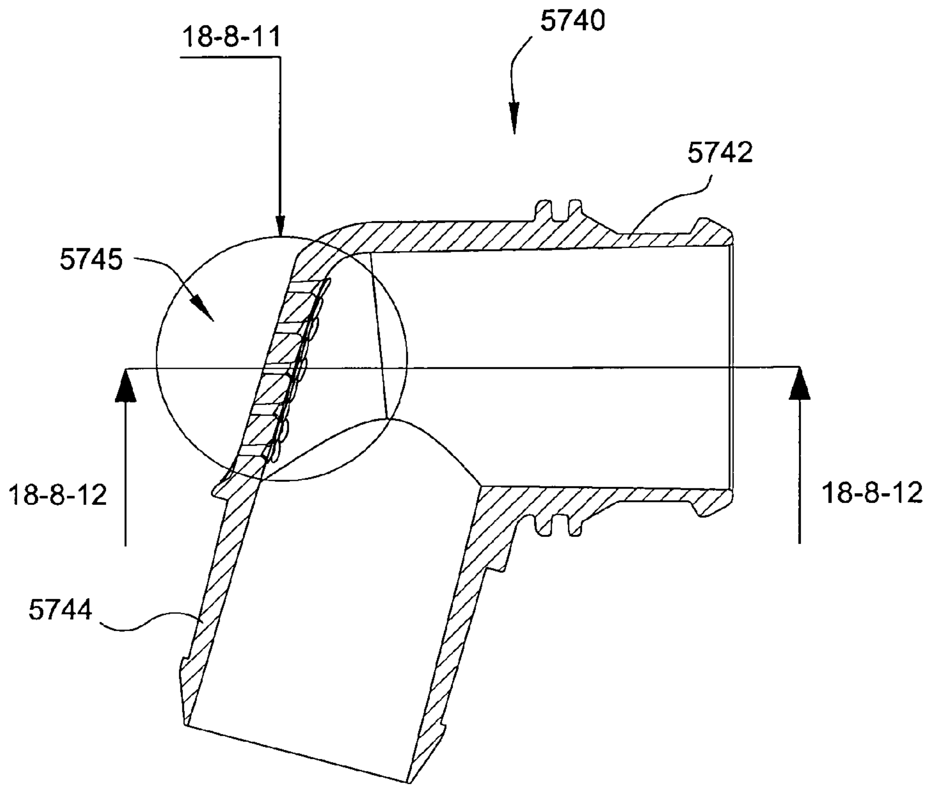

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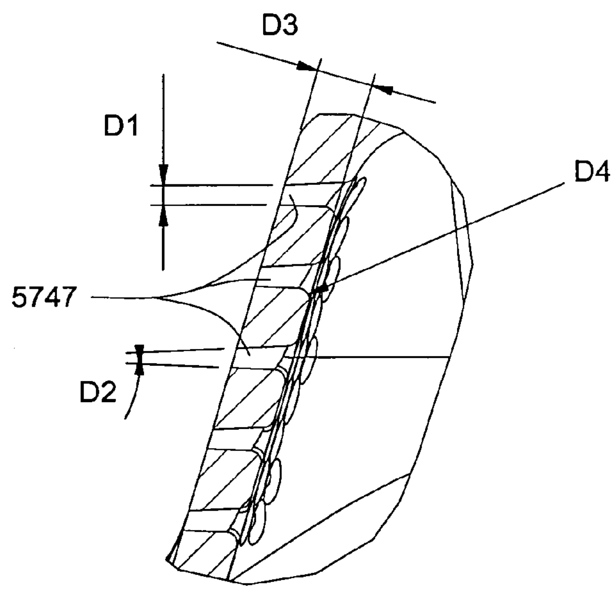

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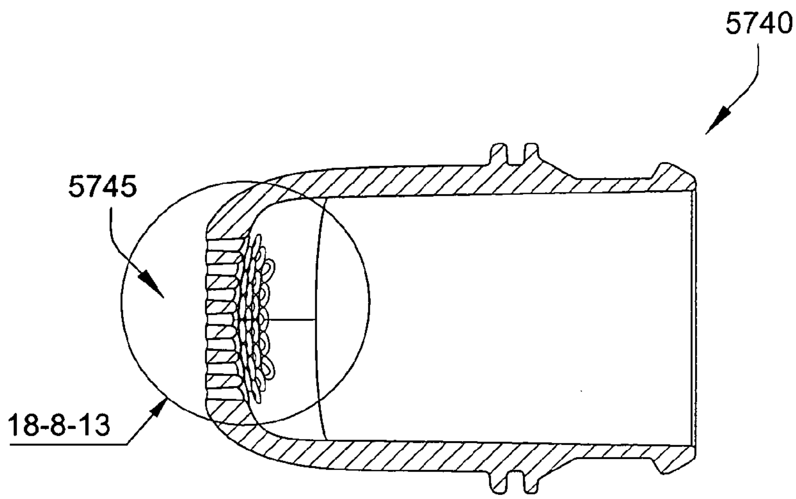

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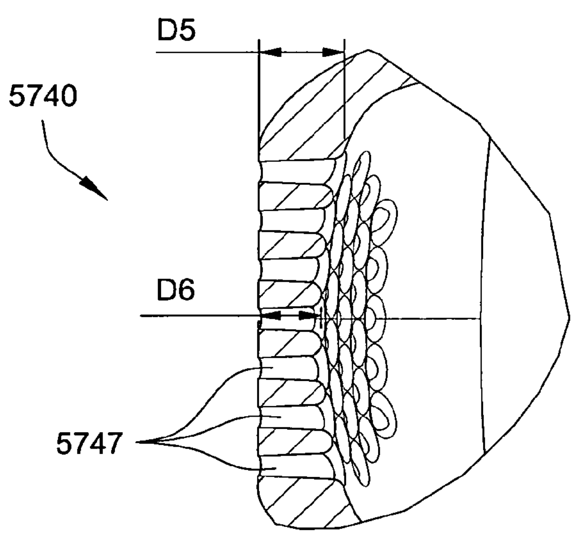

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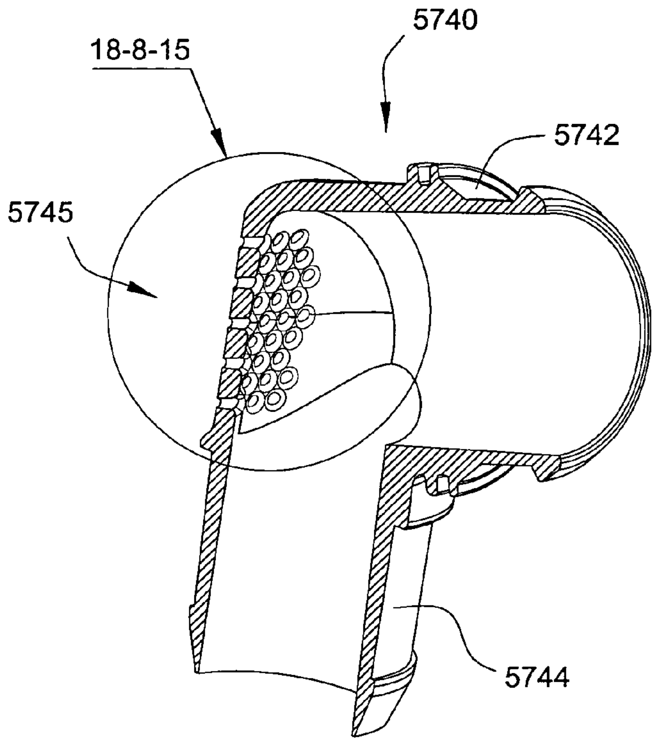

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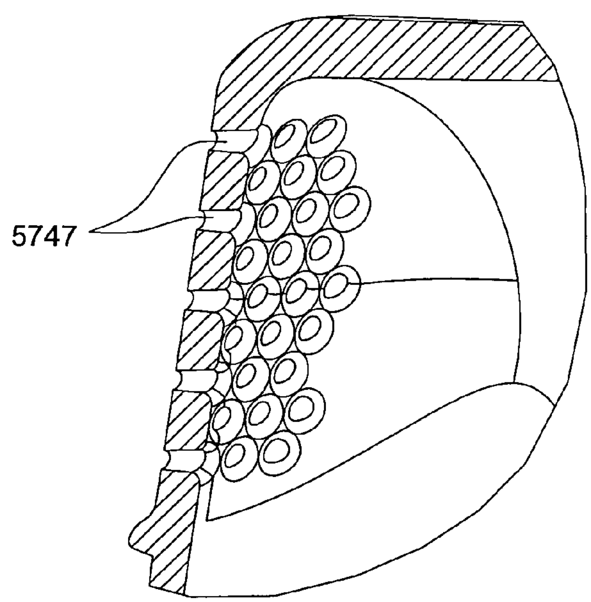

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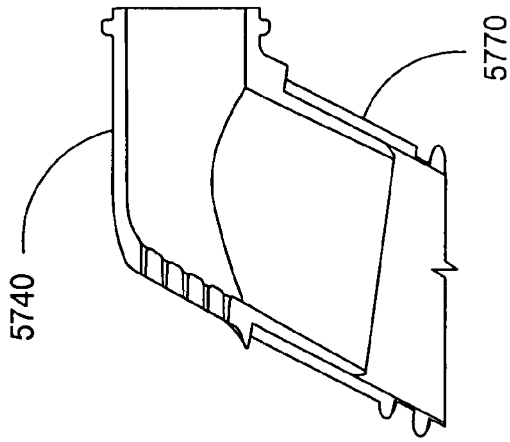

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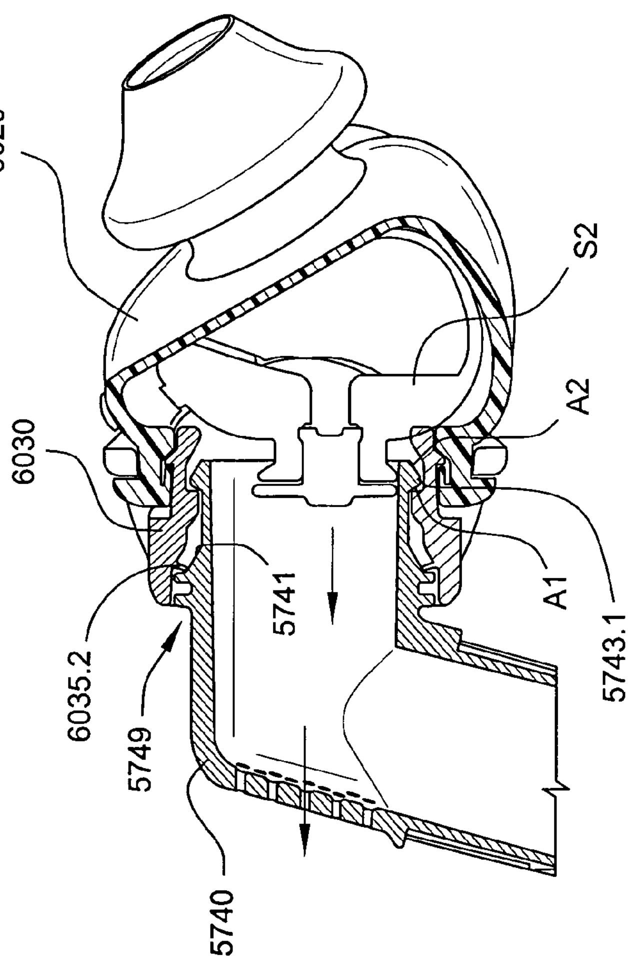

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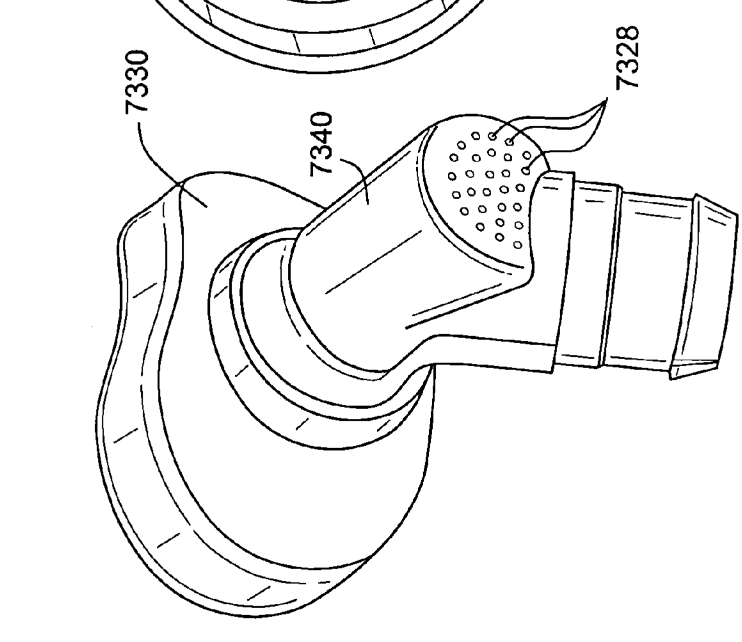
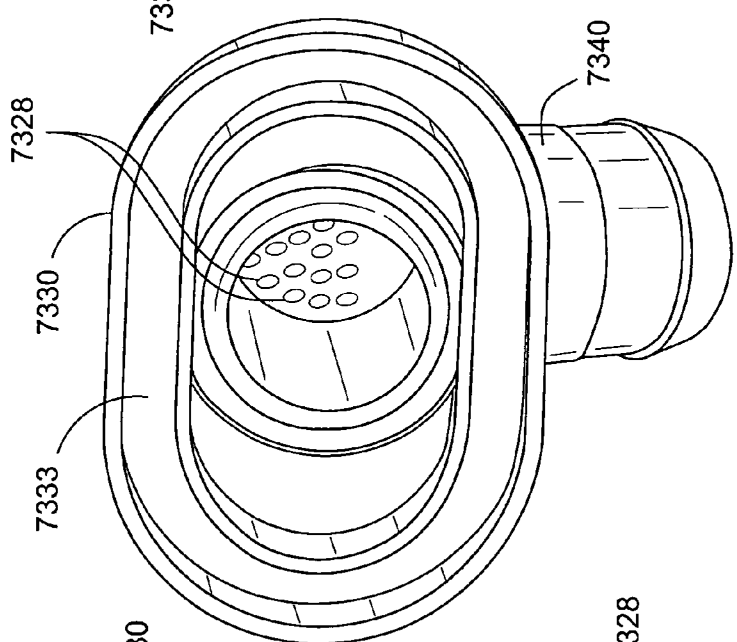


Fig. 18-9-1



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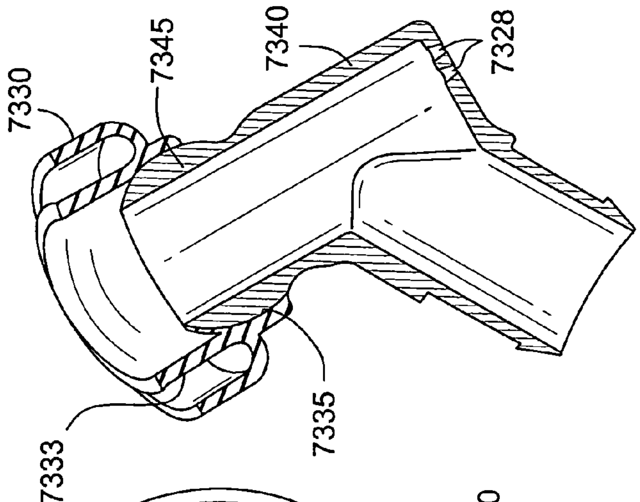

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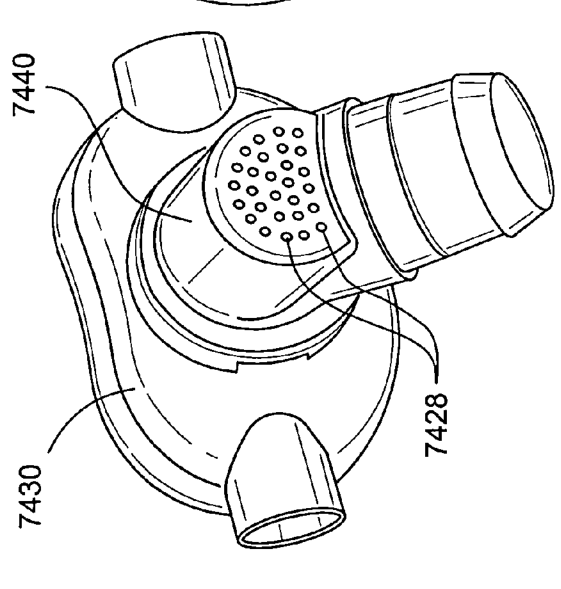

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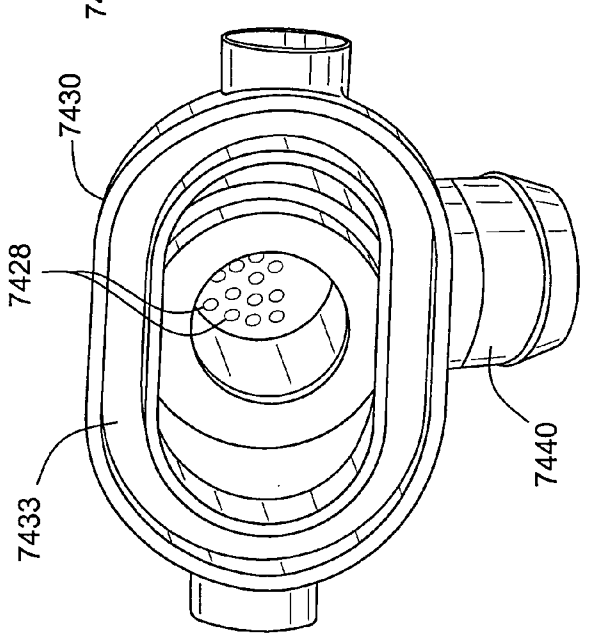

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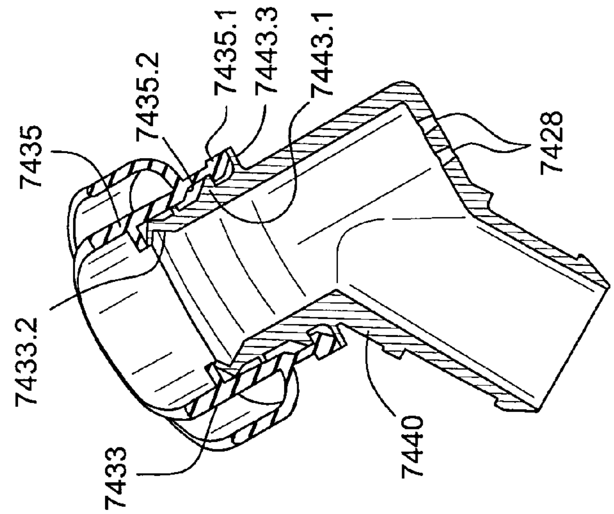

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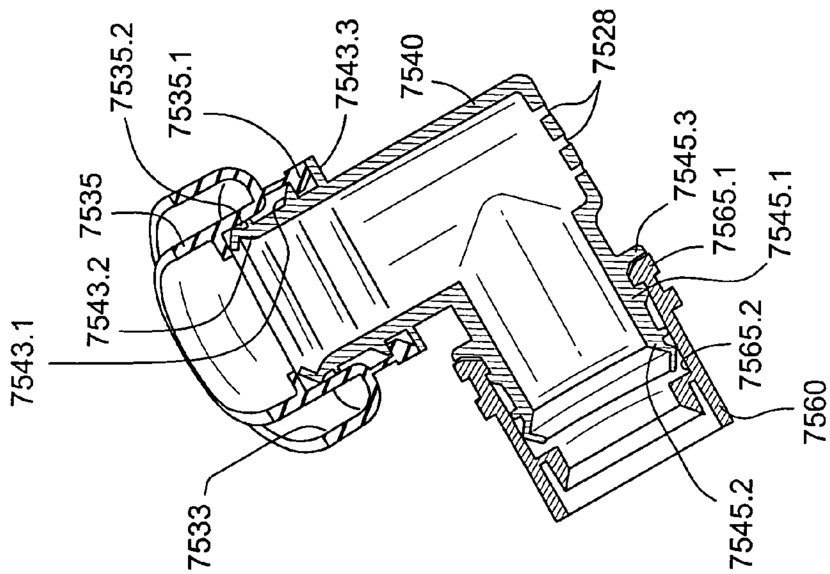

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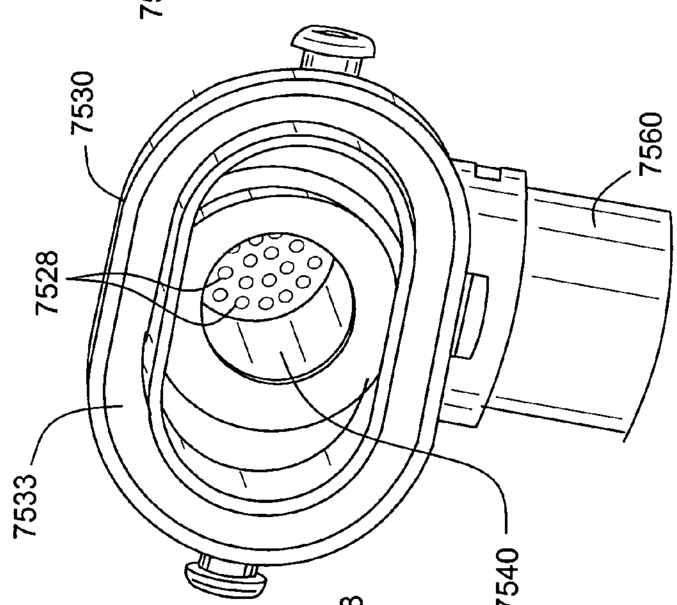

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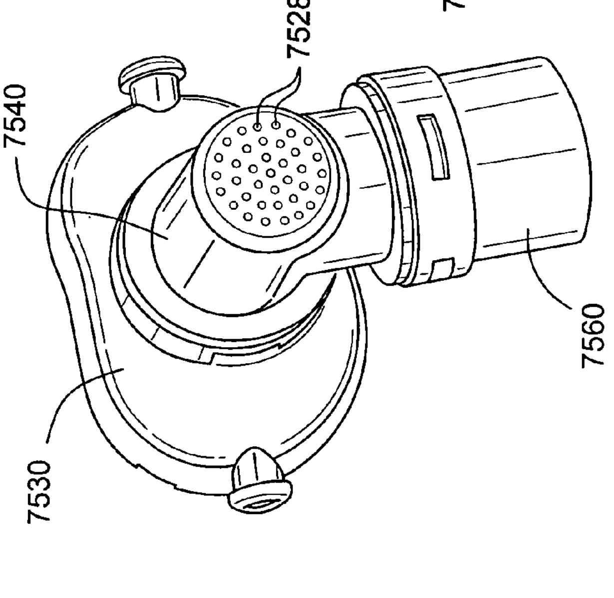

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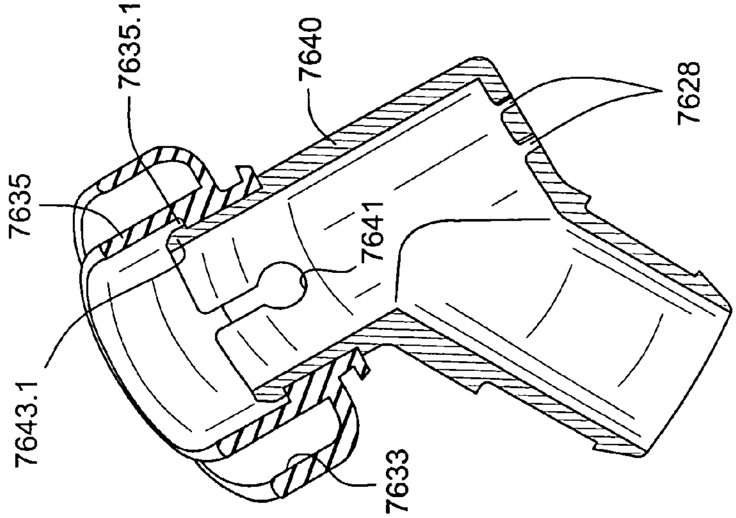

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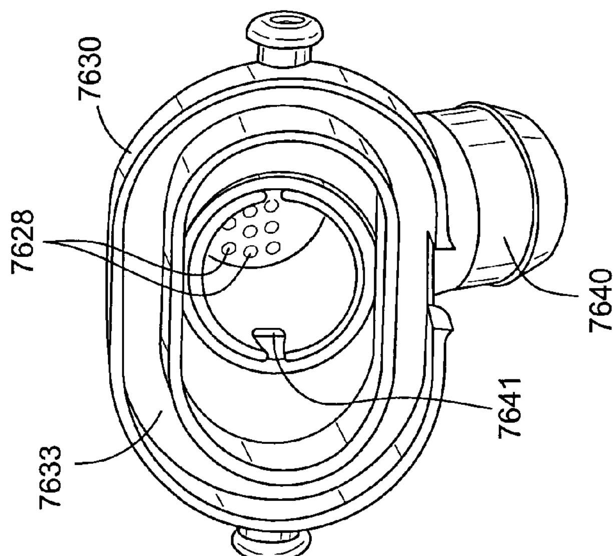

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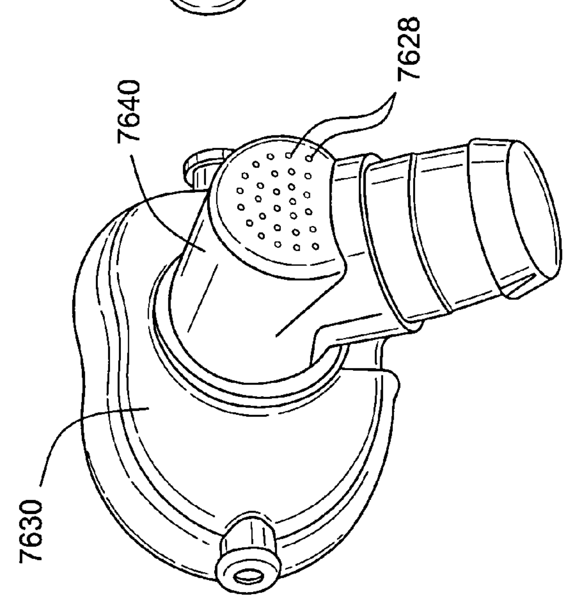

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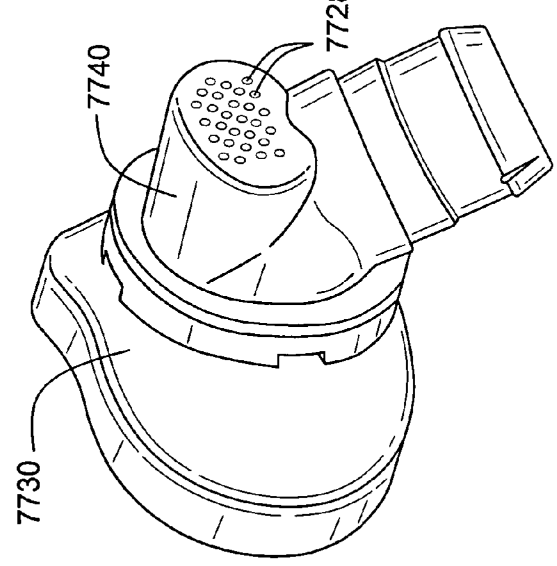

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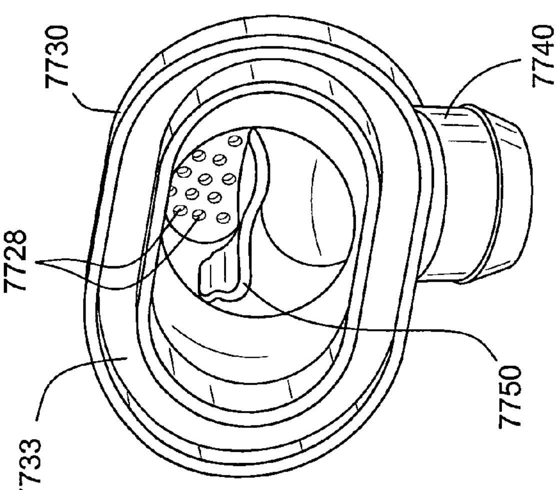

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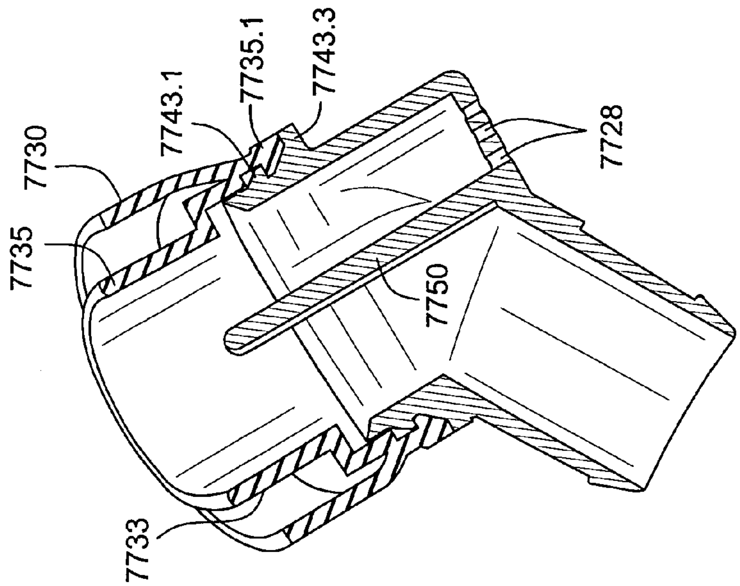

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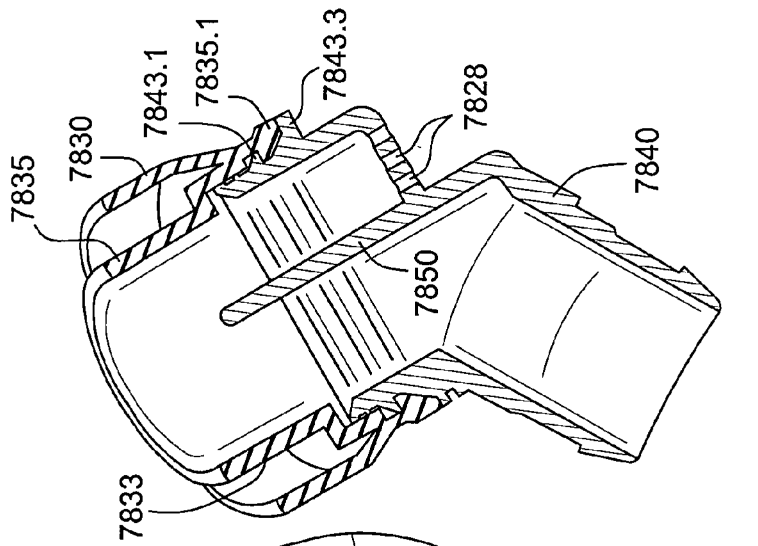

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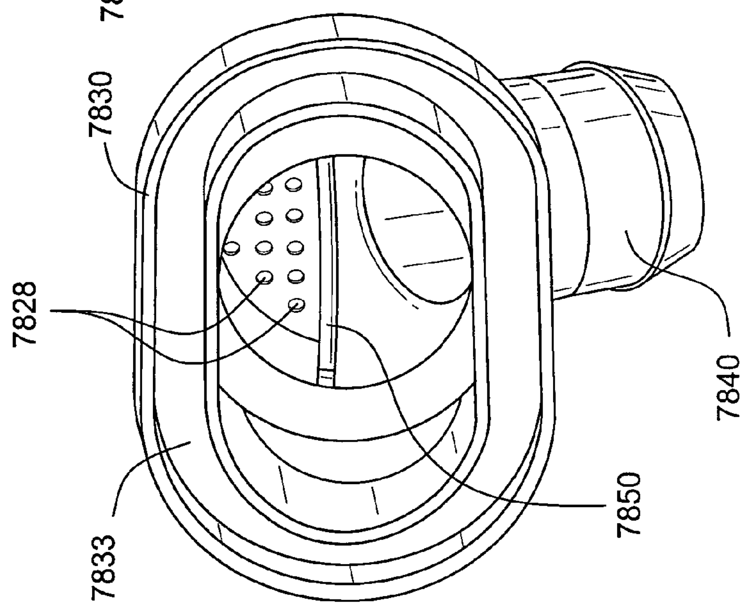

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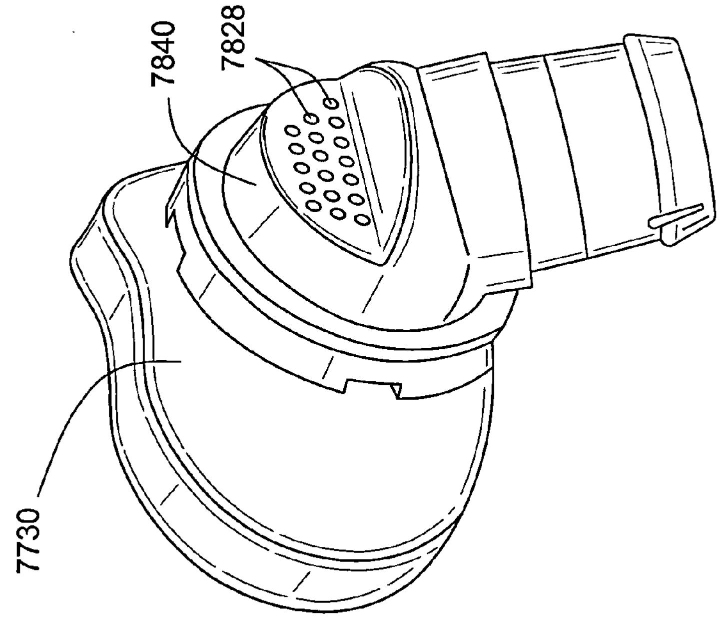

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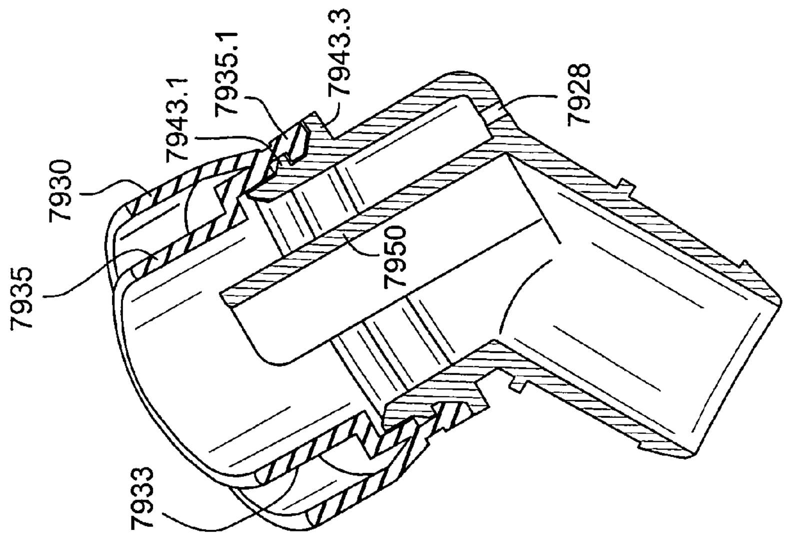

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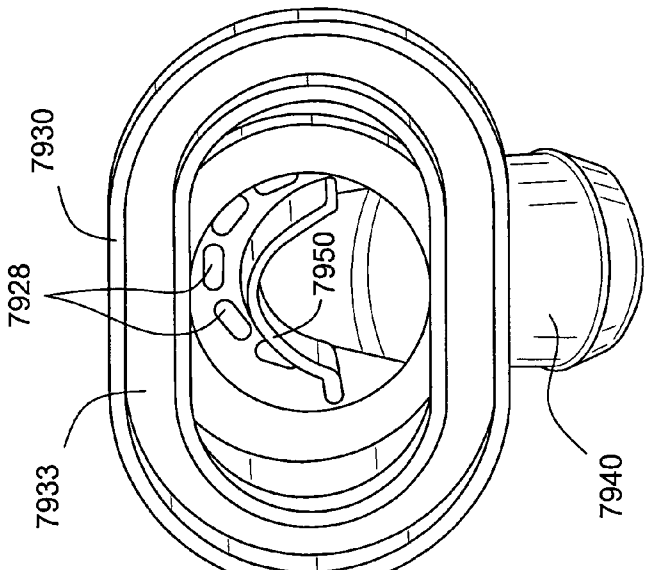

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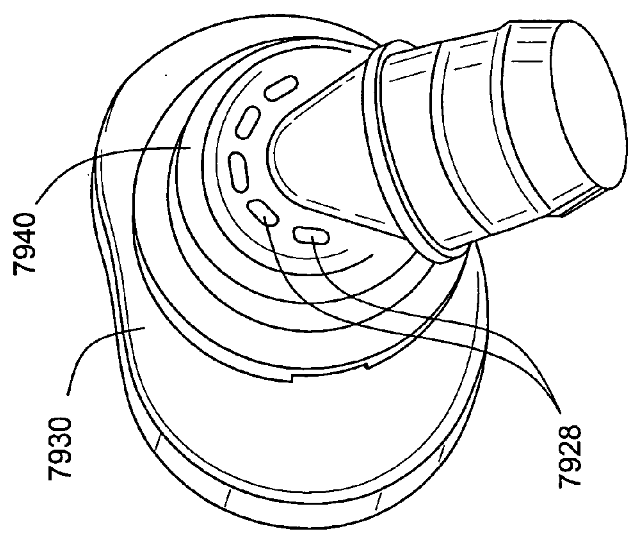

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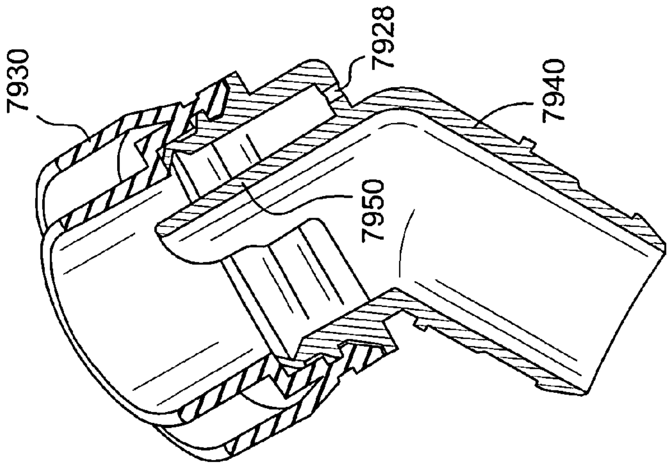
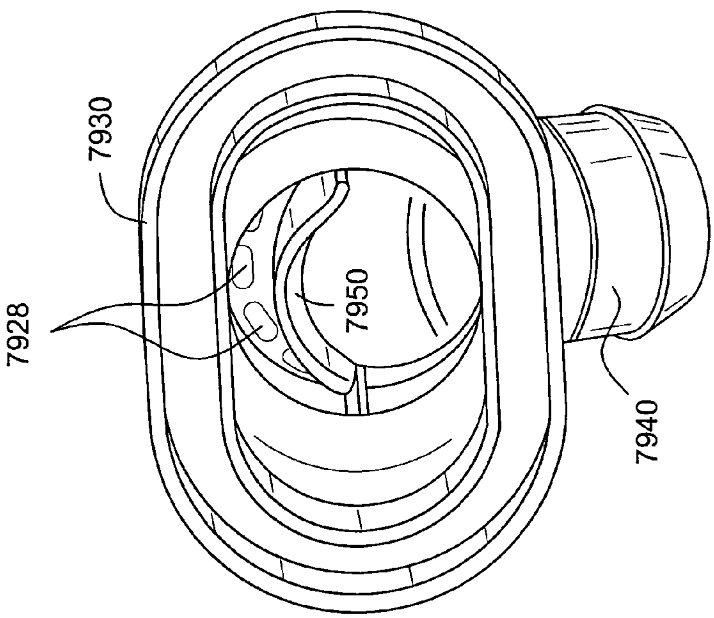


Fig. 18-16-3



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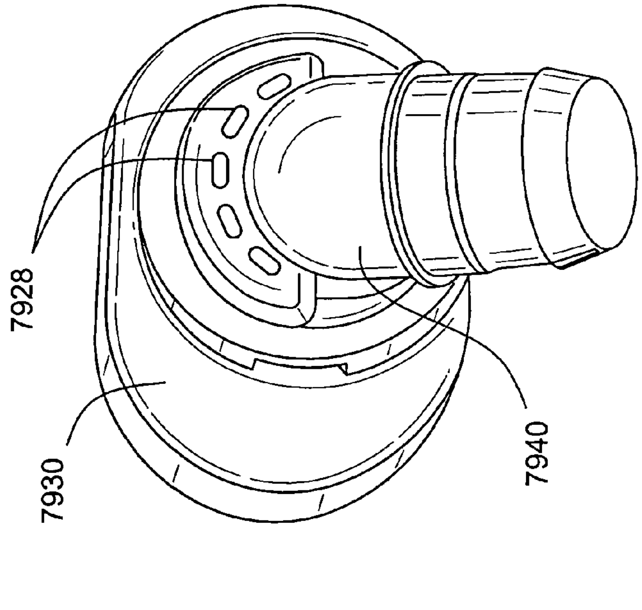

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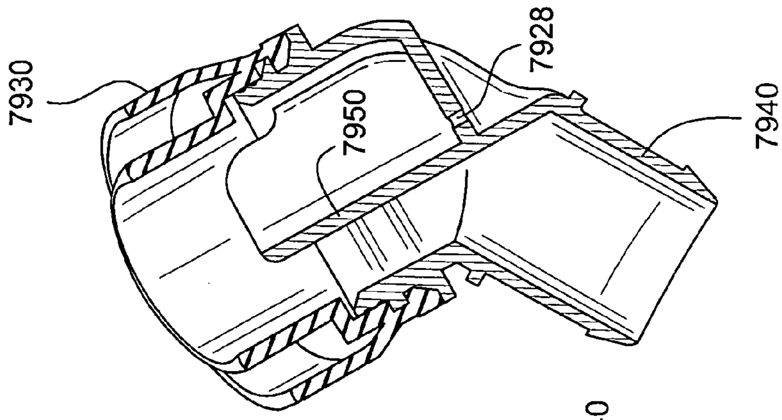

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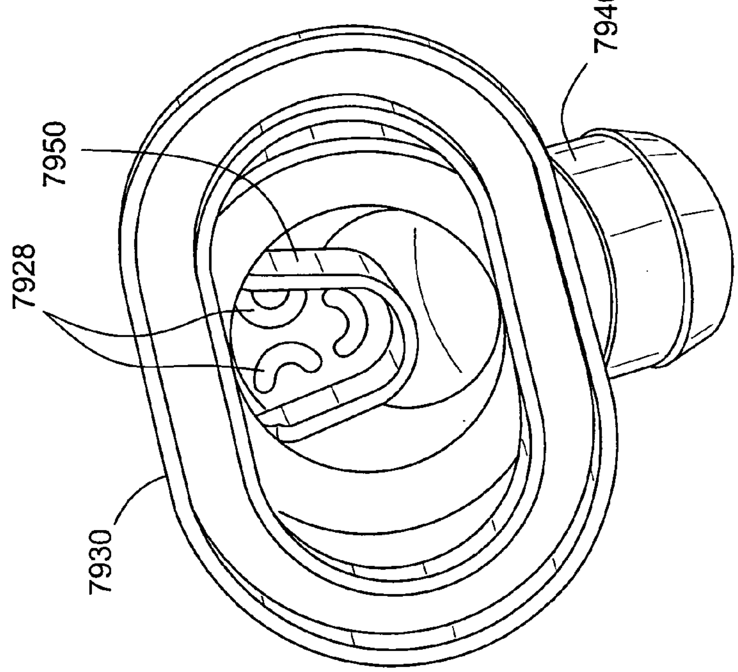

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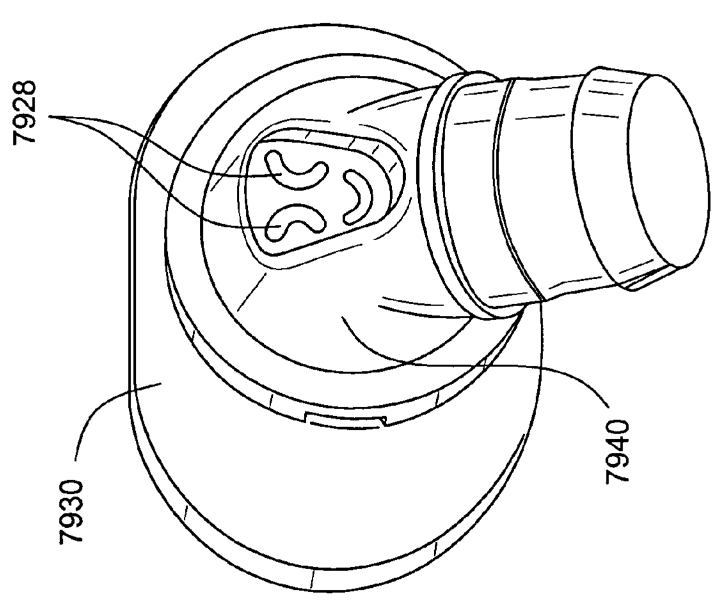

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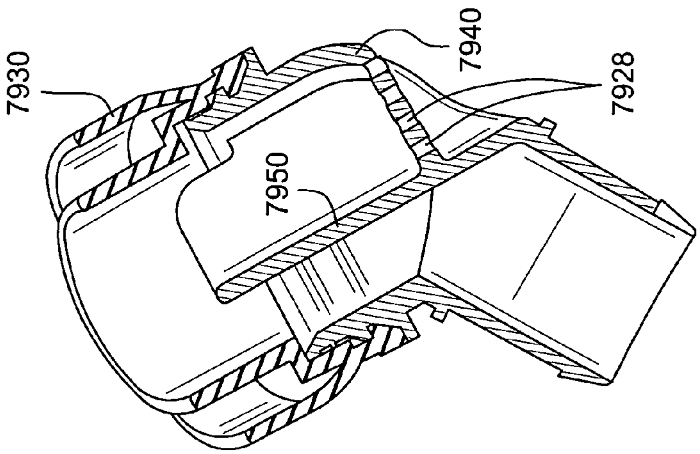

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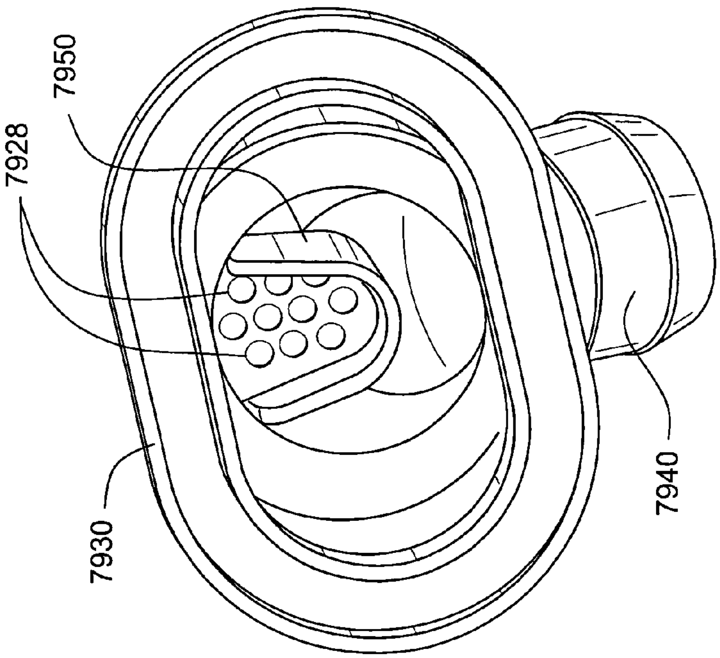

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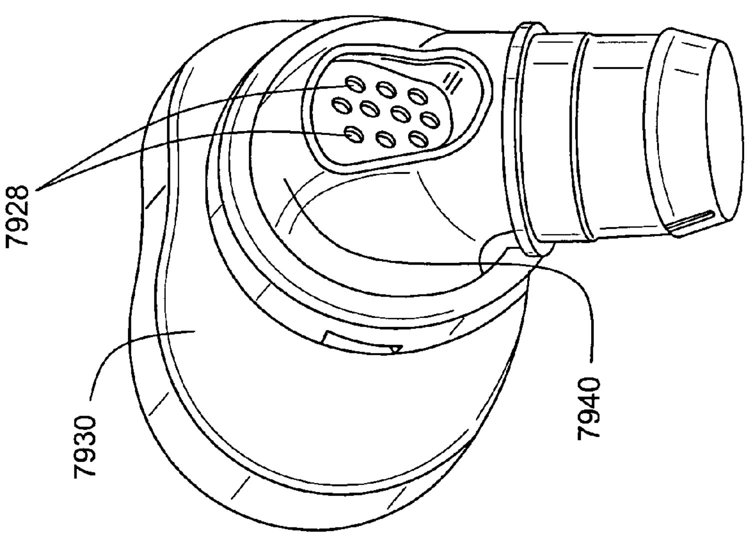

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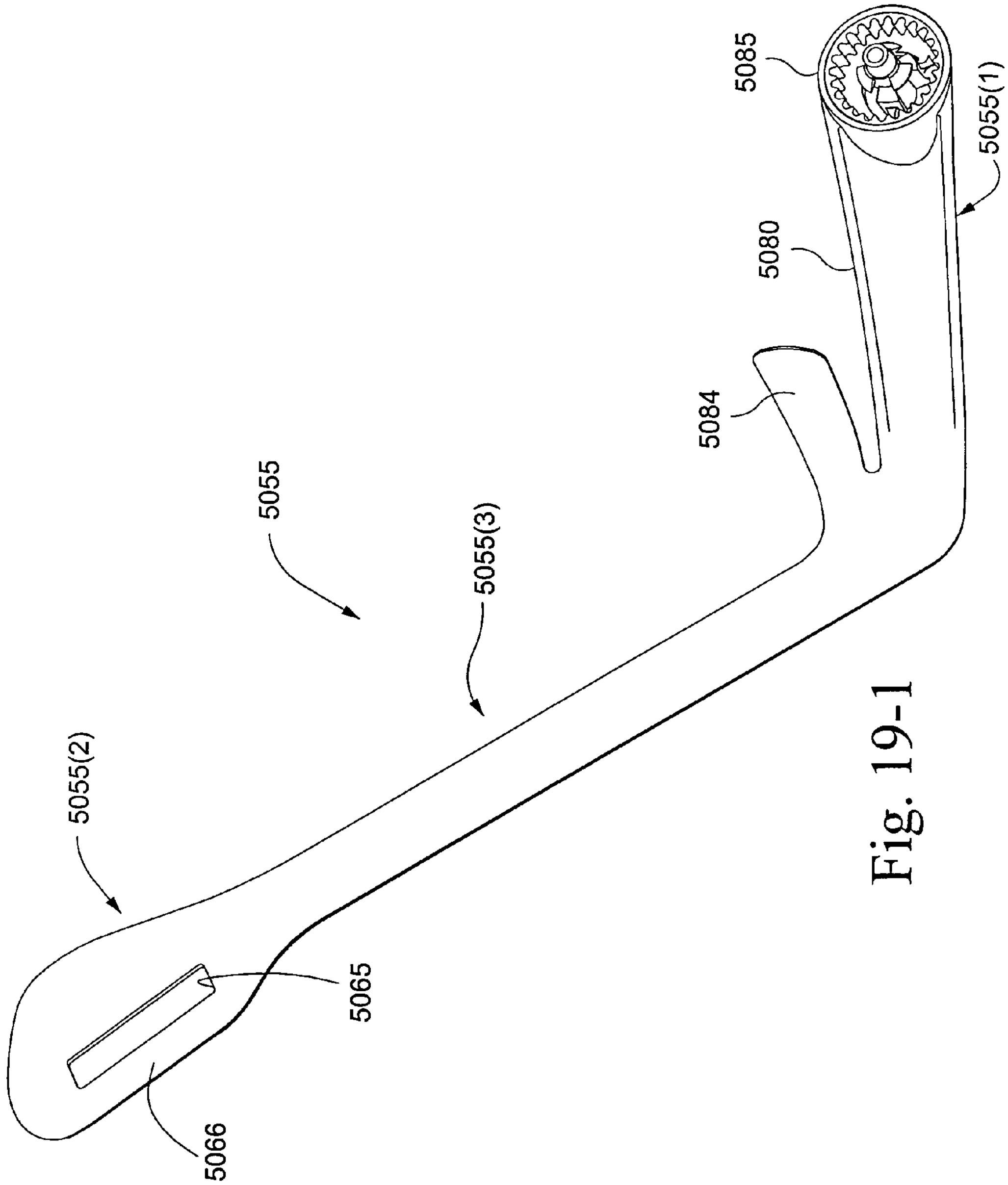
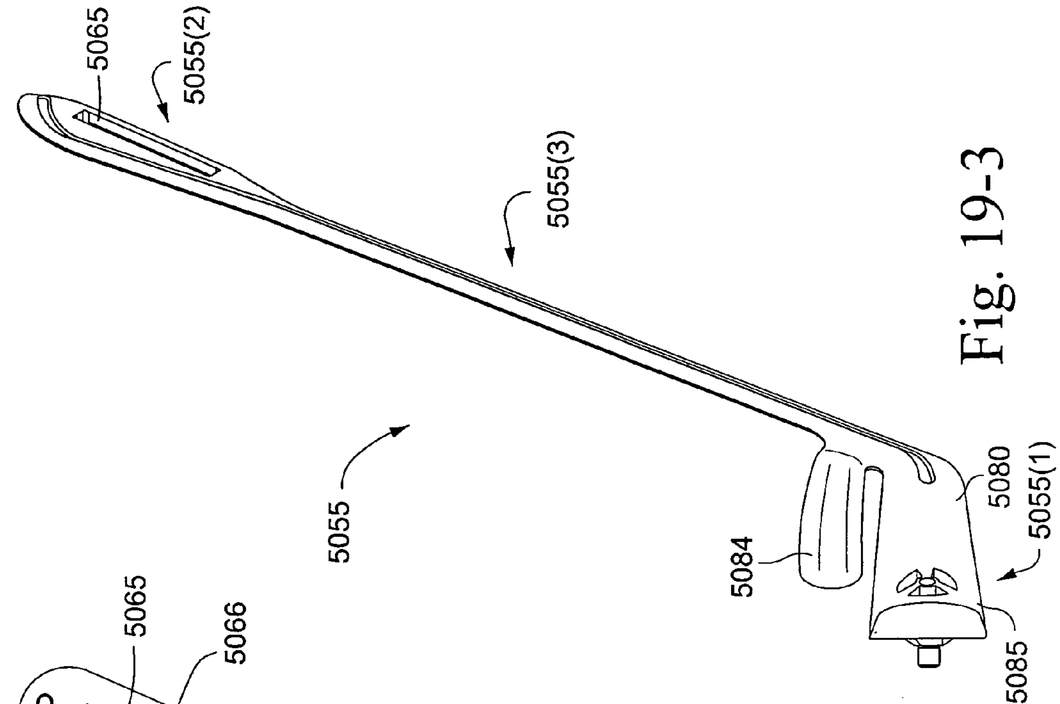


Fig. 19-1



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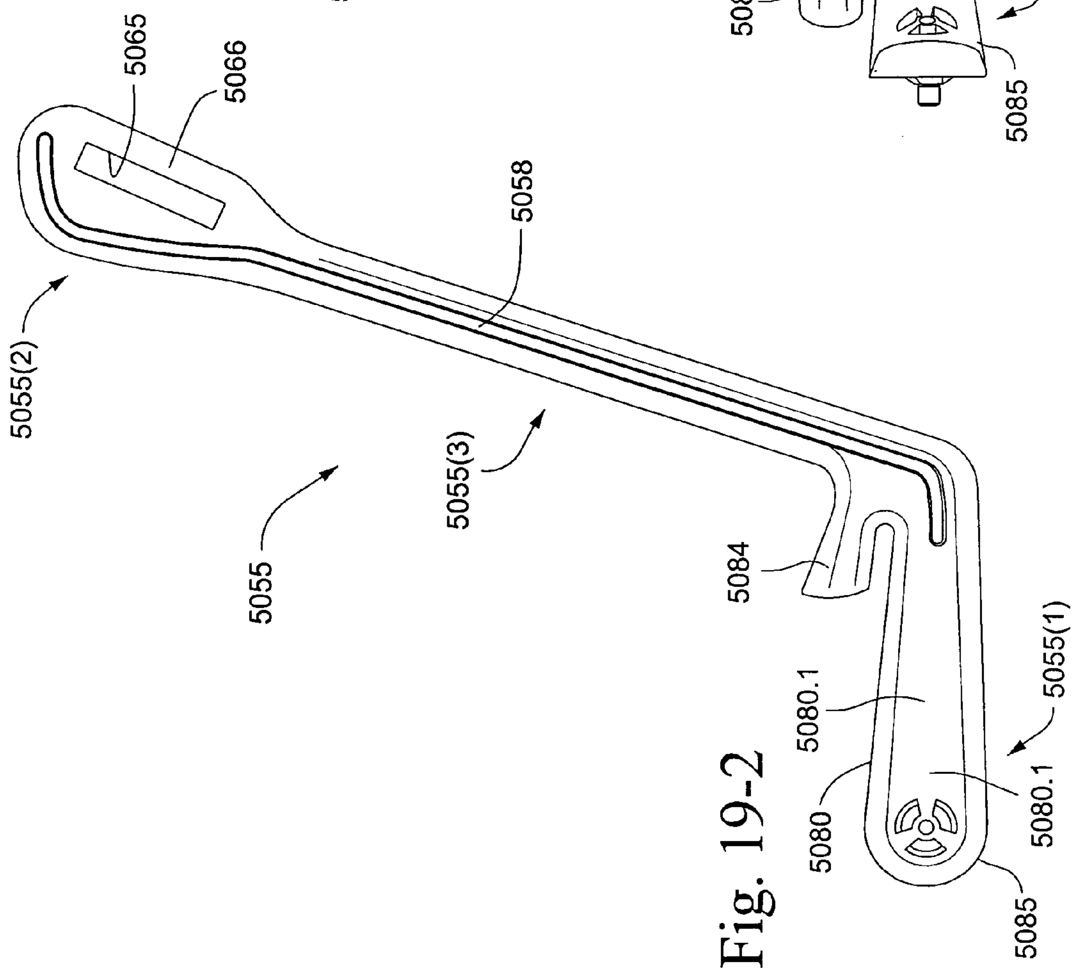

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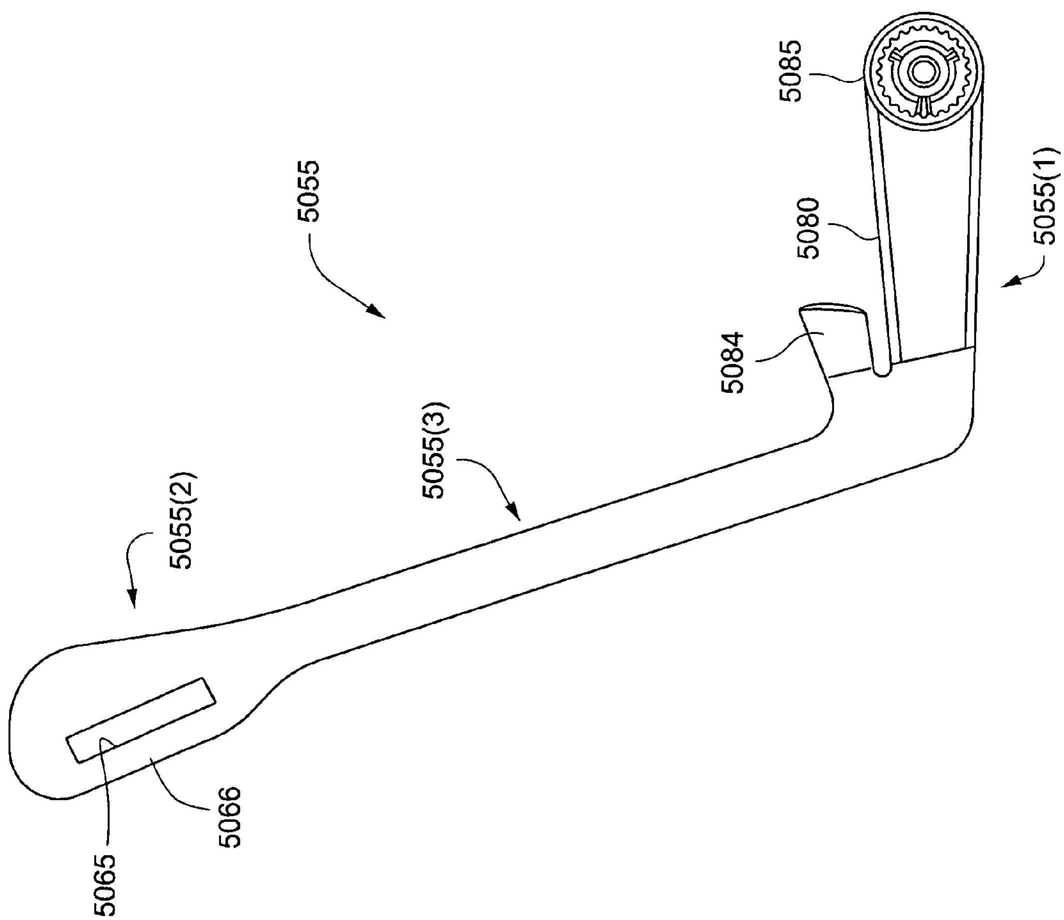


Fig. 19-4

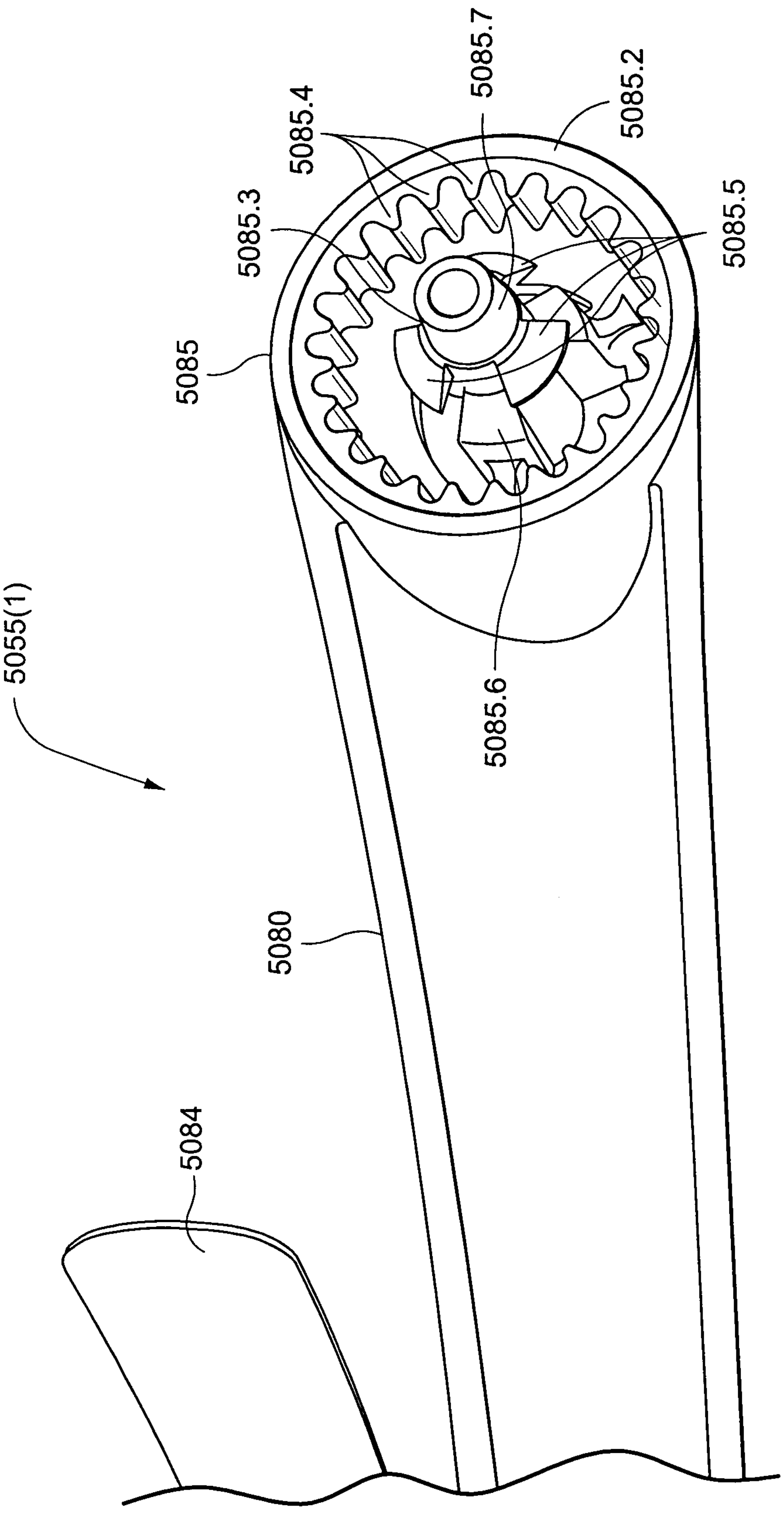
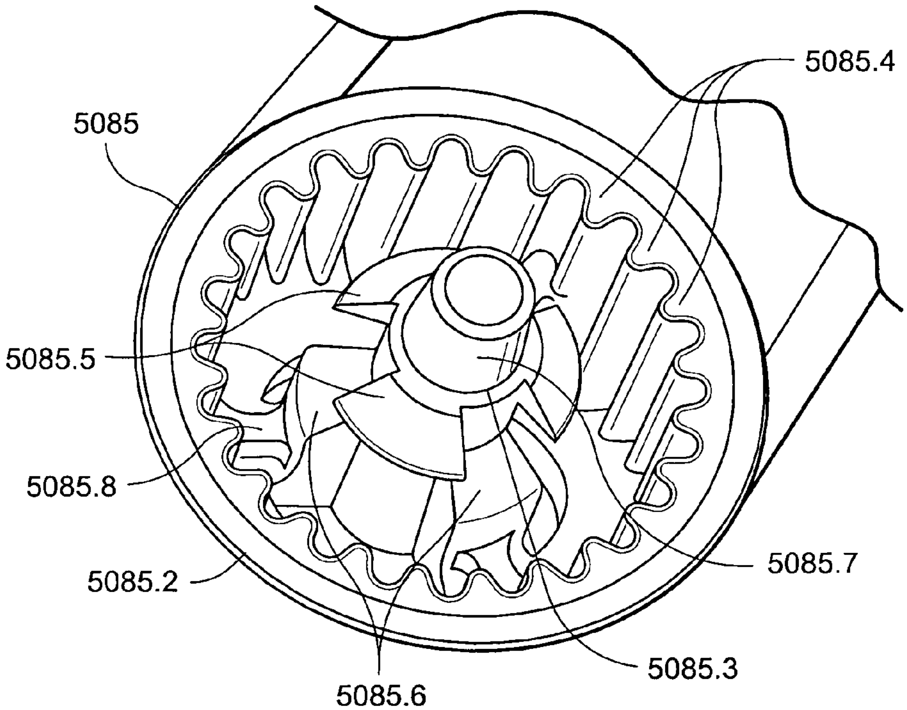


Fig. 19-5



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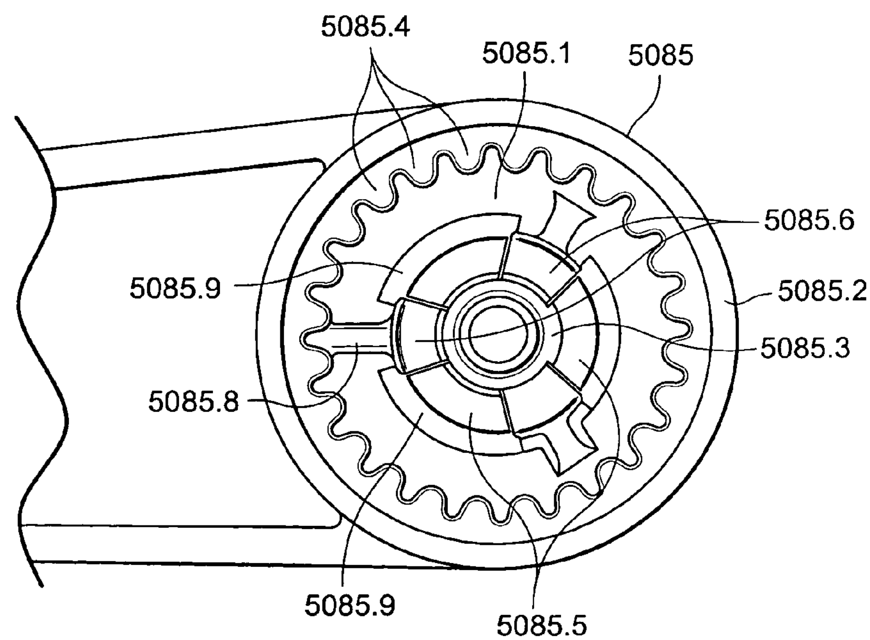

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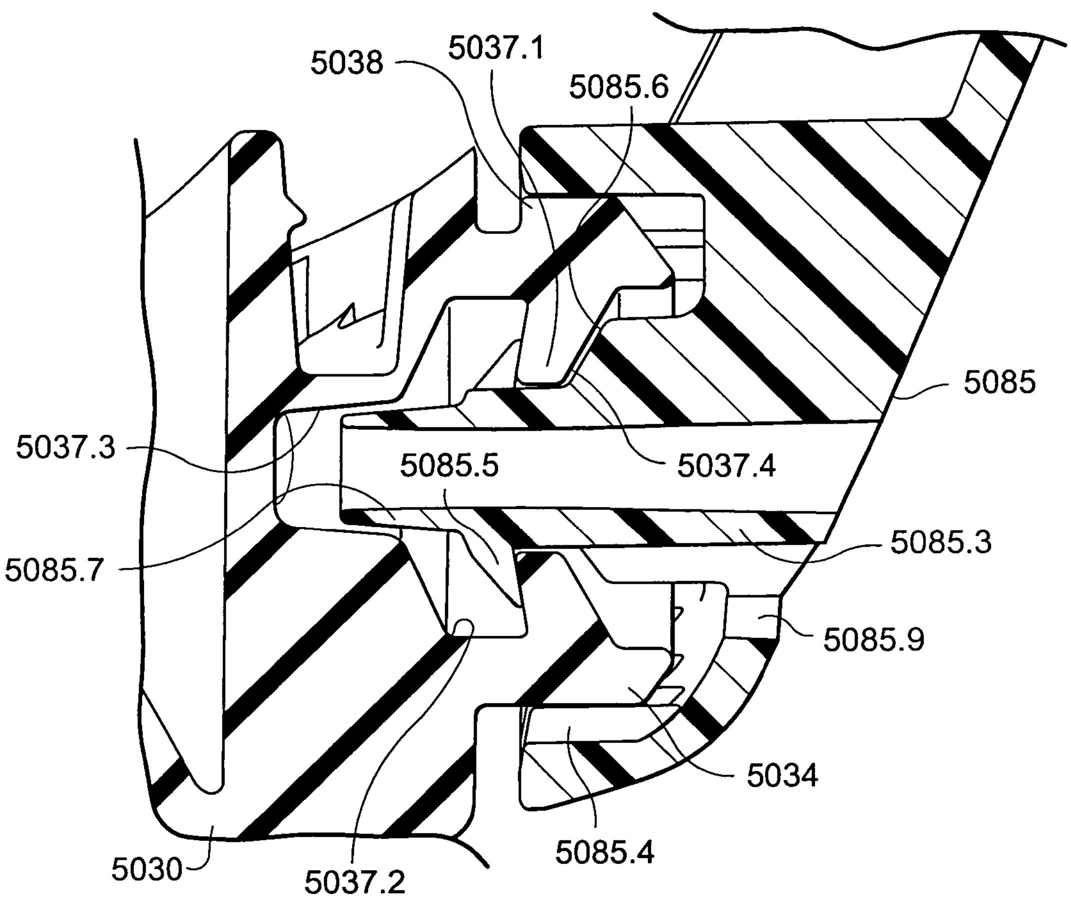
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Fig. 19-8

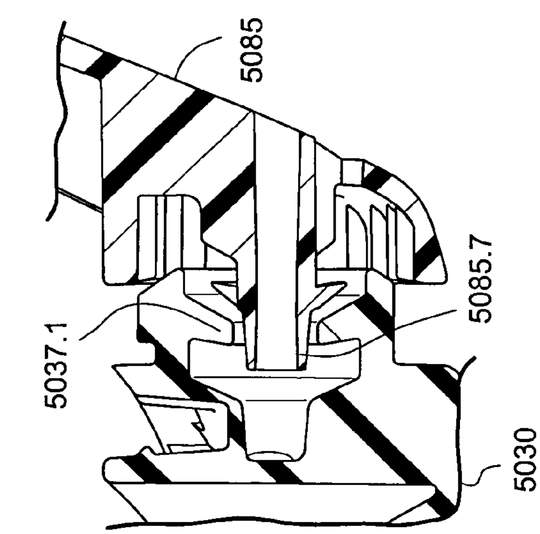
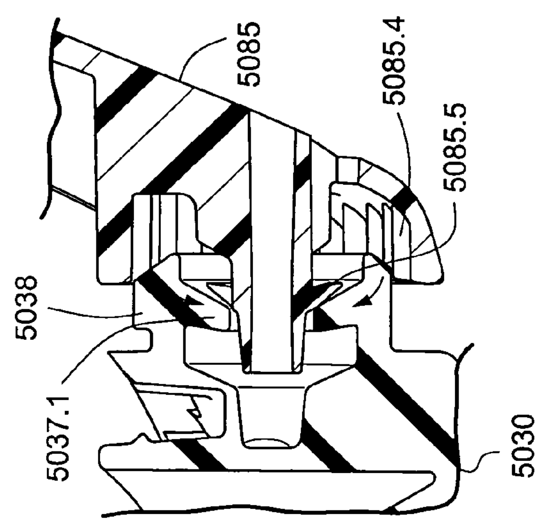


Fig. 19-9-1



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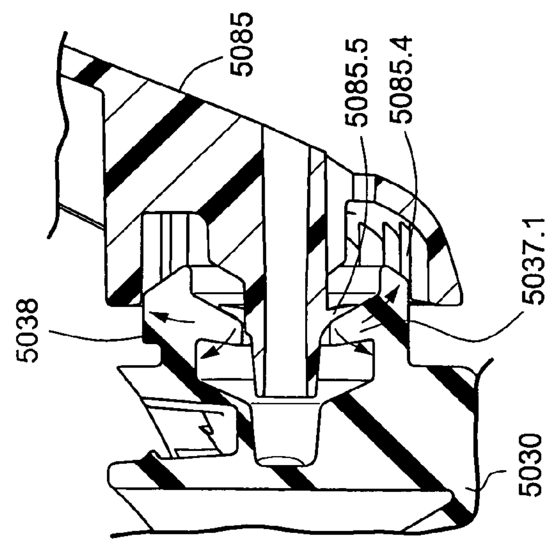

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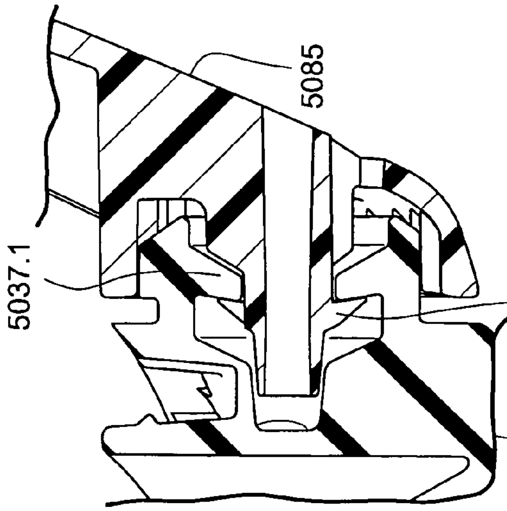
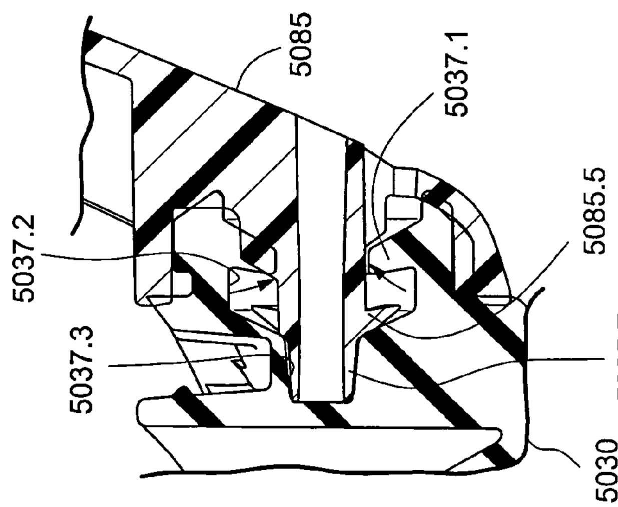


Fig. 19-9-6



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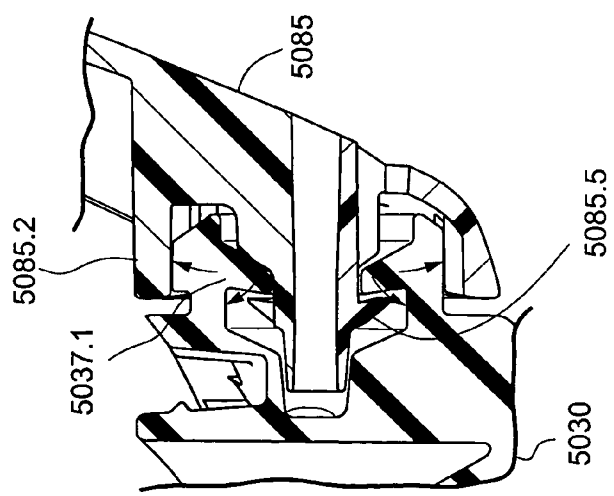

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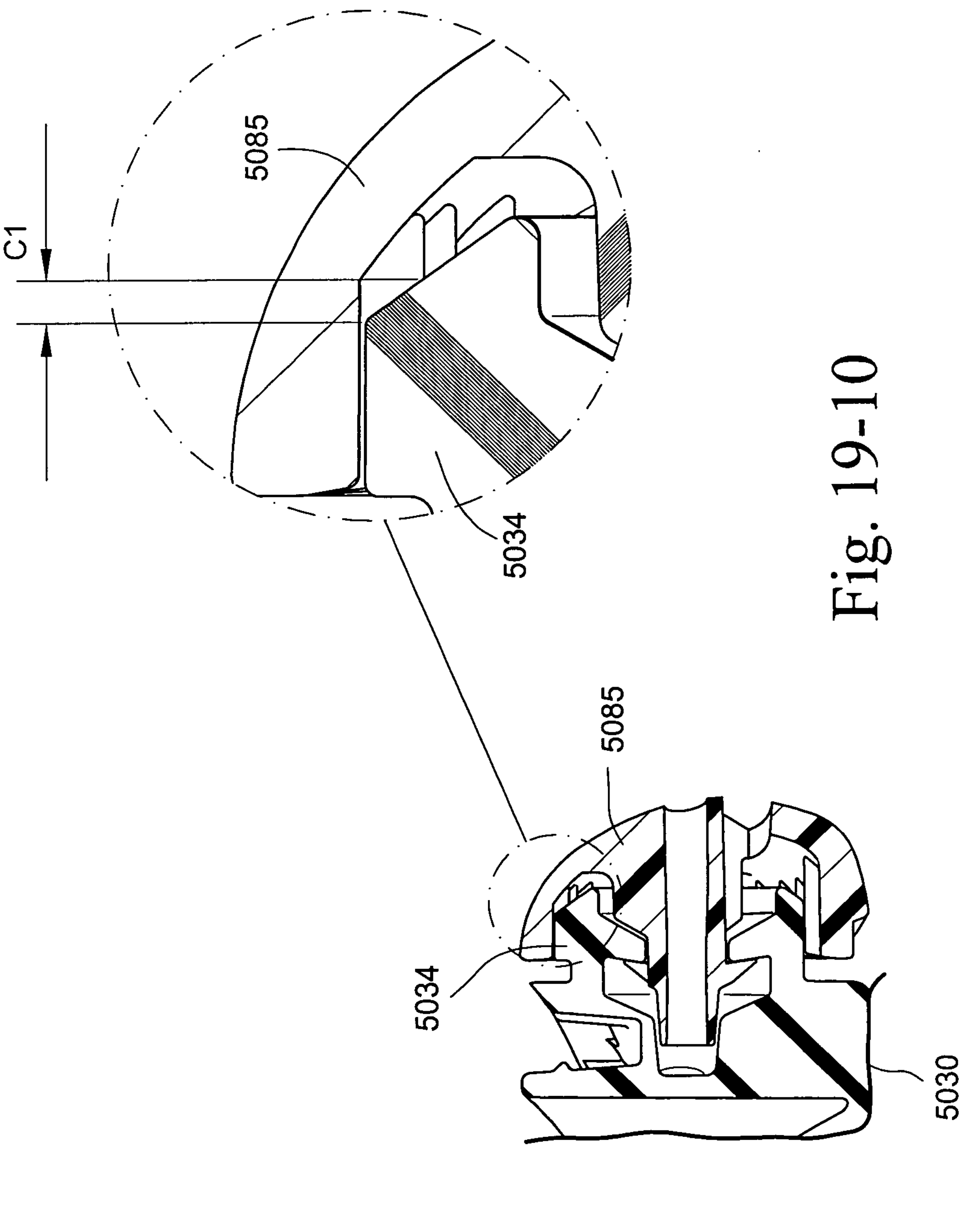


Fig. 19-10

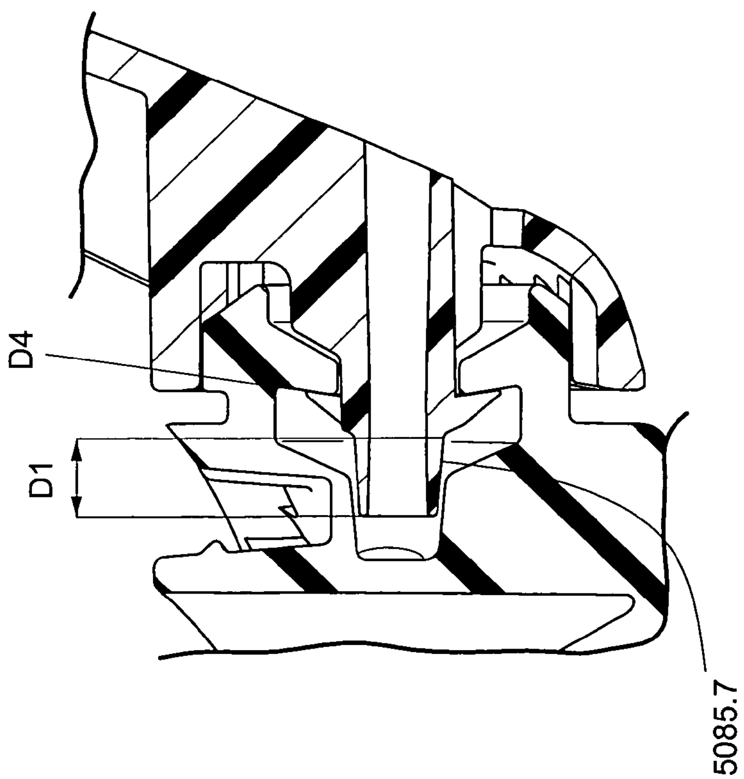


Fig. 19-11

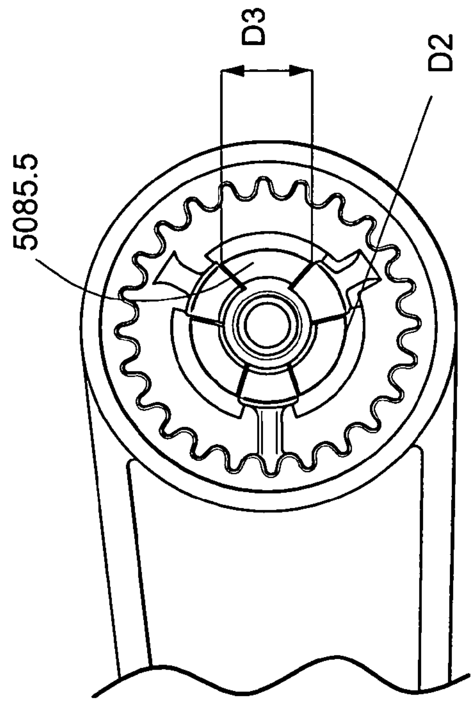


Fig. 19-12

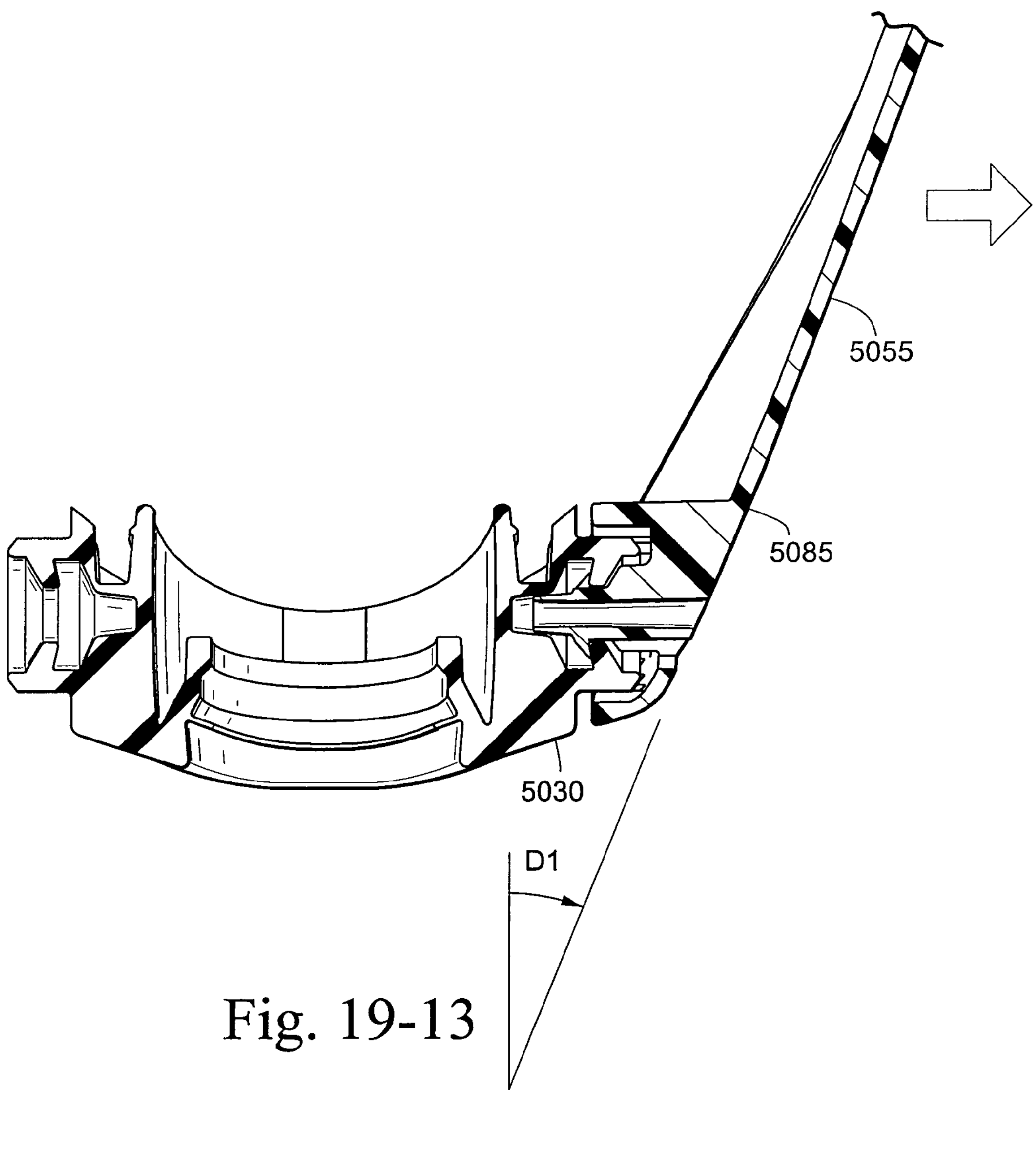


Fig. 19-13

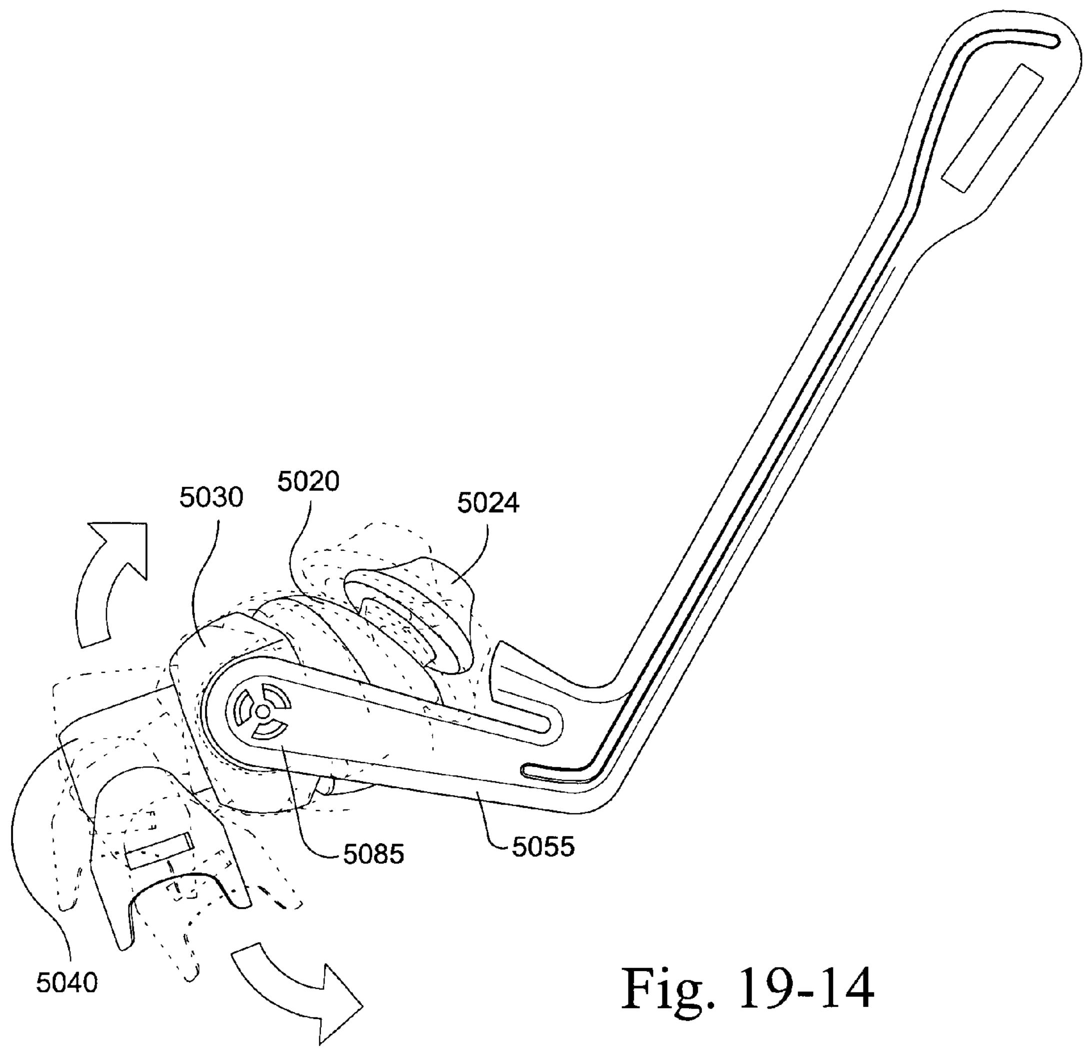


Fig. 19-14

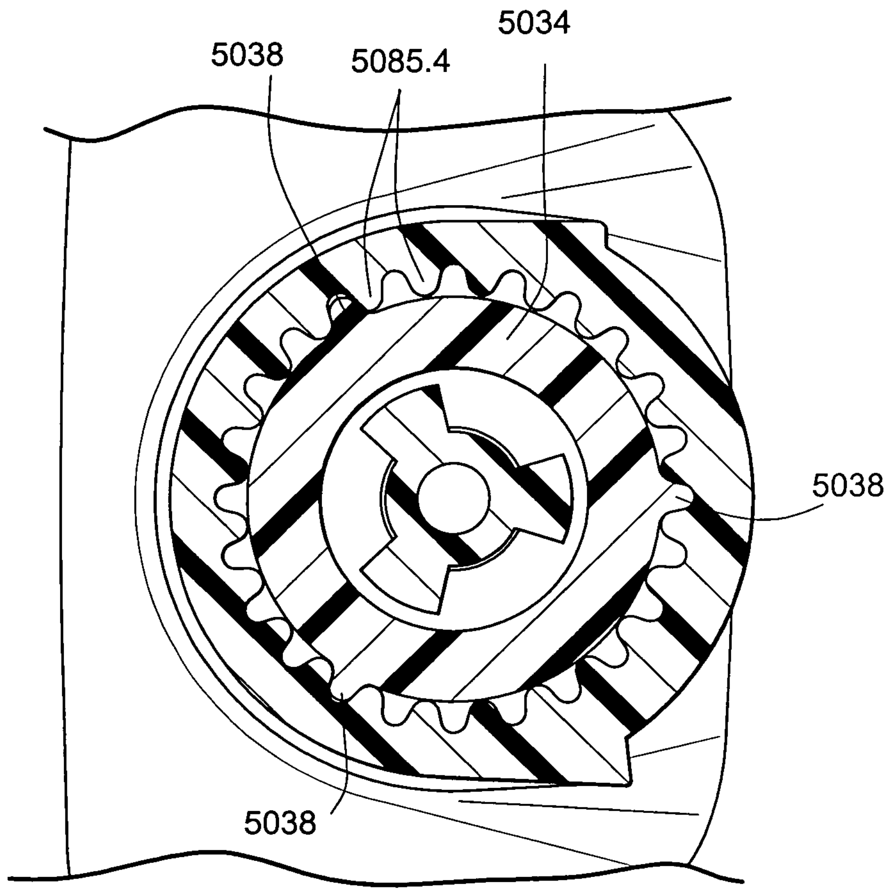


Fig. 19-15-1

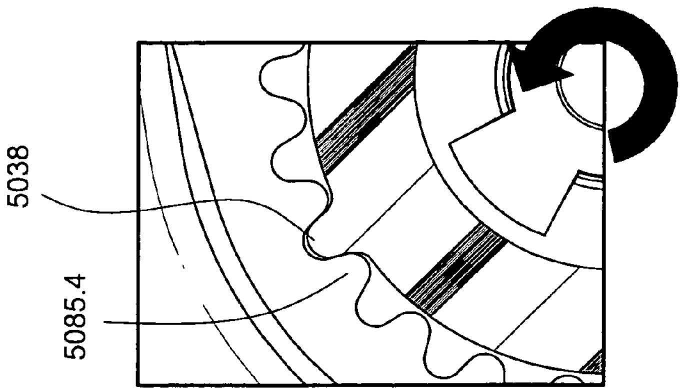
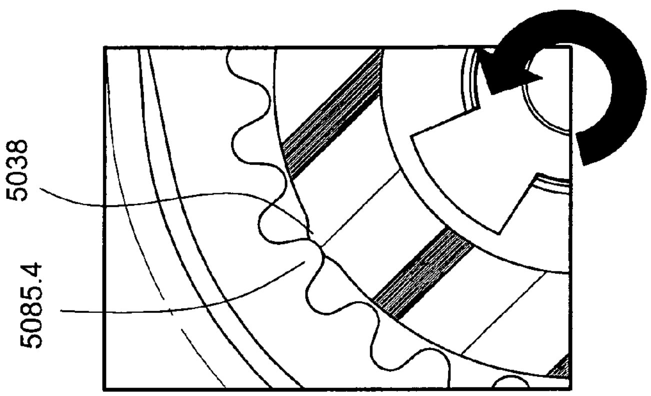


Fig. 19-15-5



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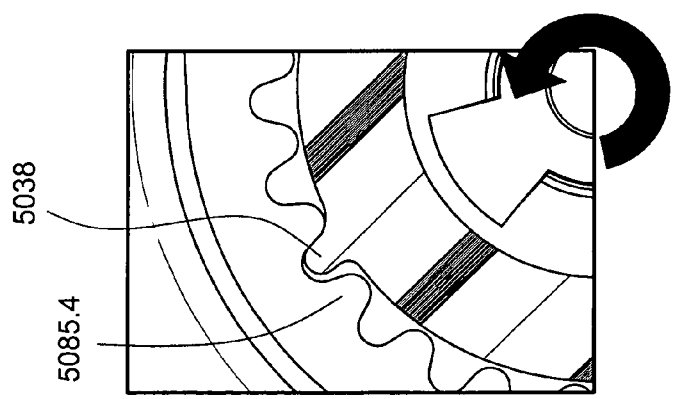

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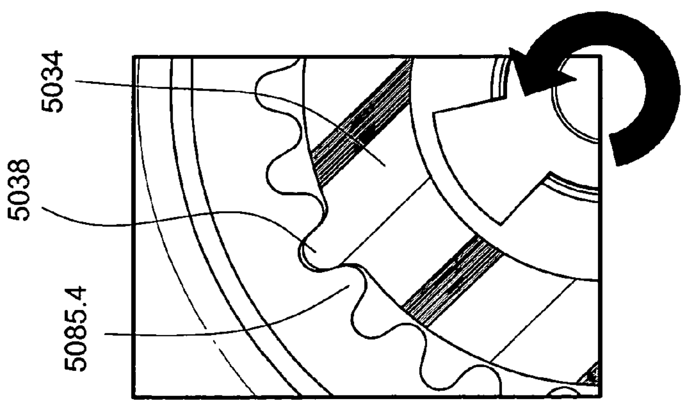

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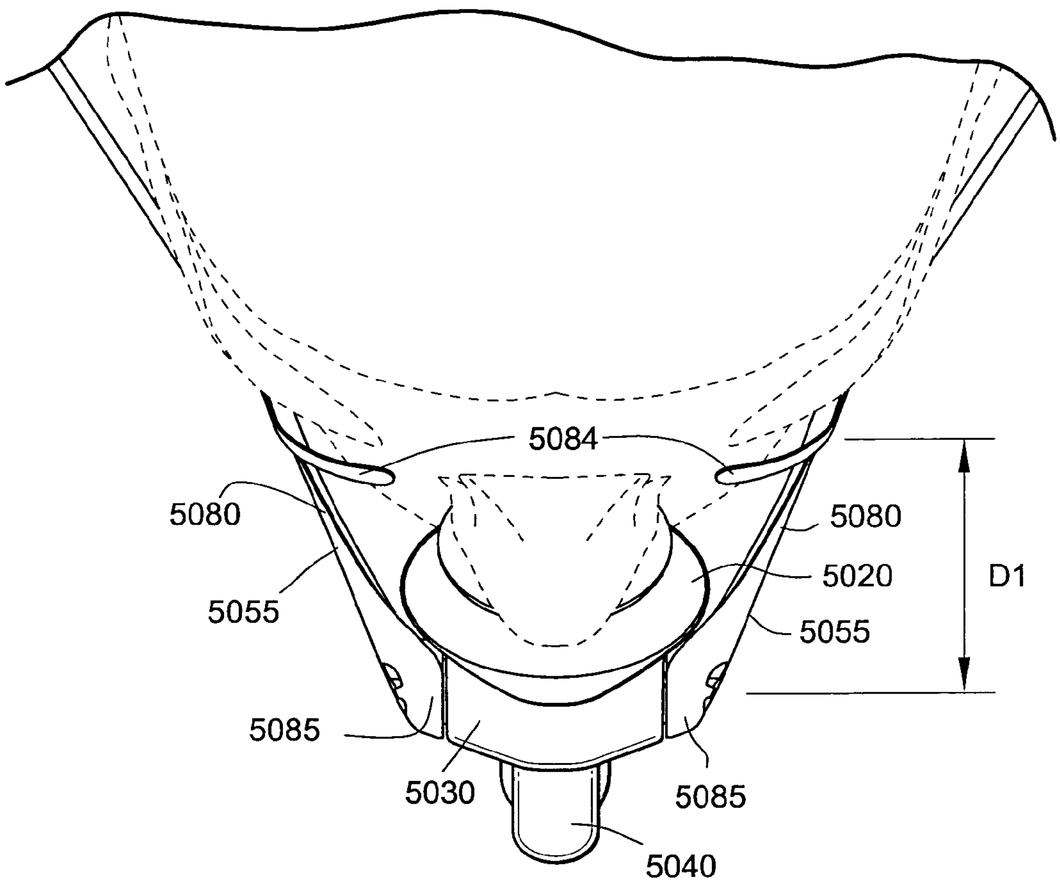


Fig. 19-16

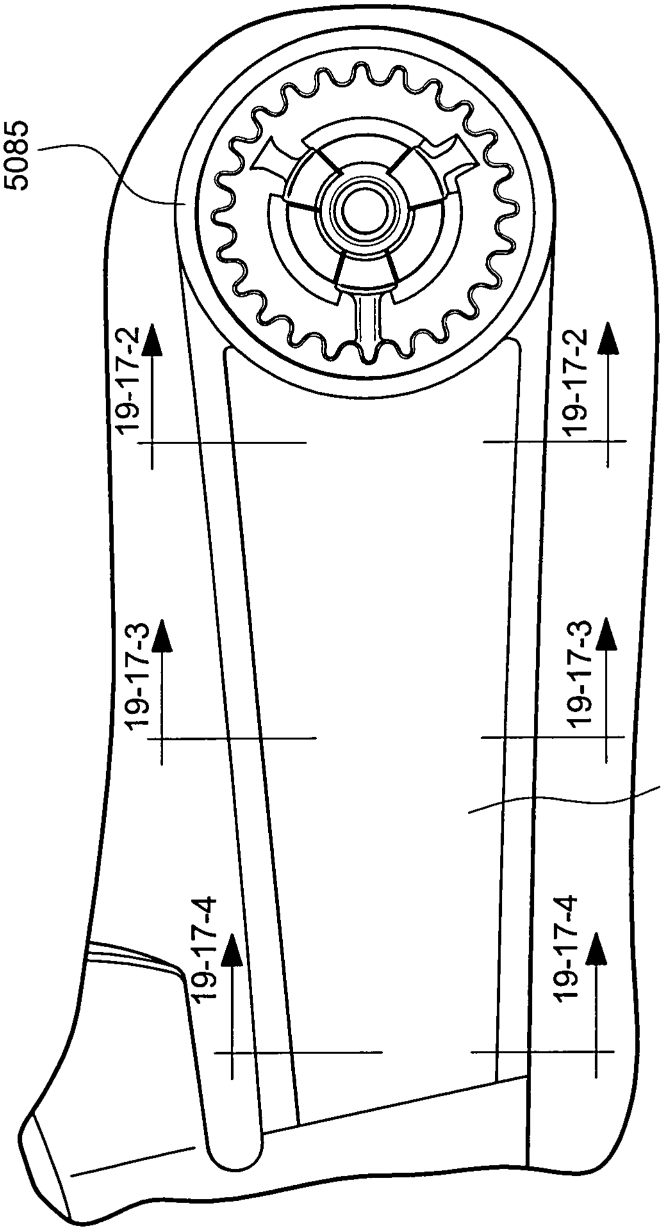
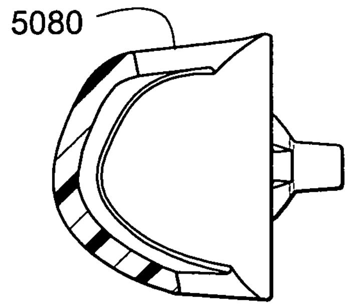


Fig. 19-17-1



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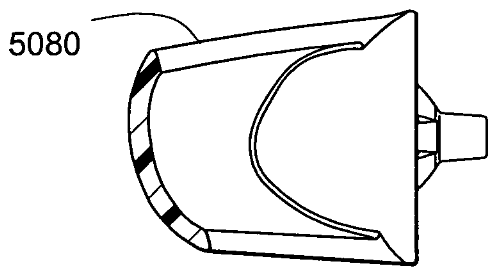

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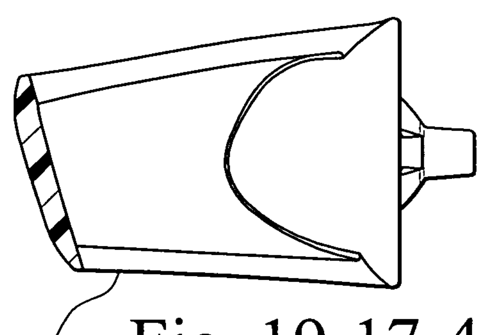

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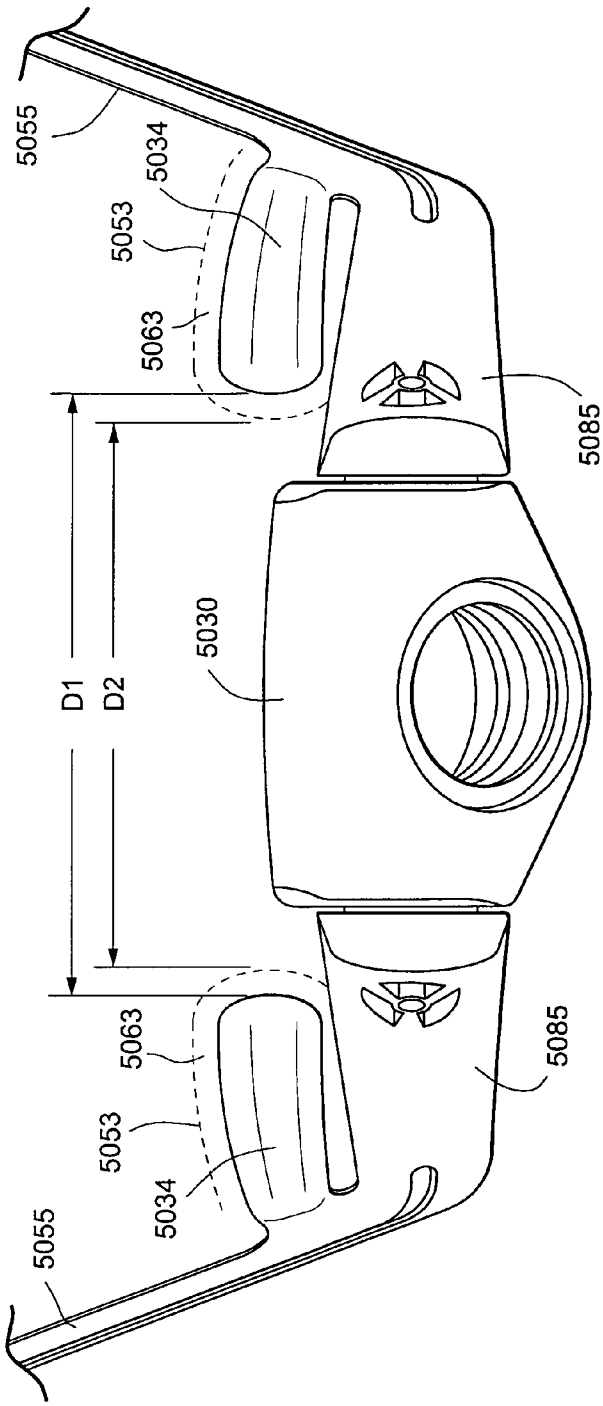


Fig. 19-18

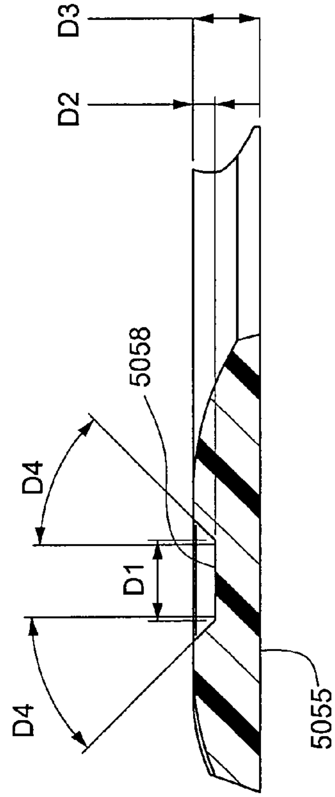


Fig. 19-19

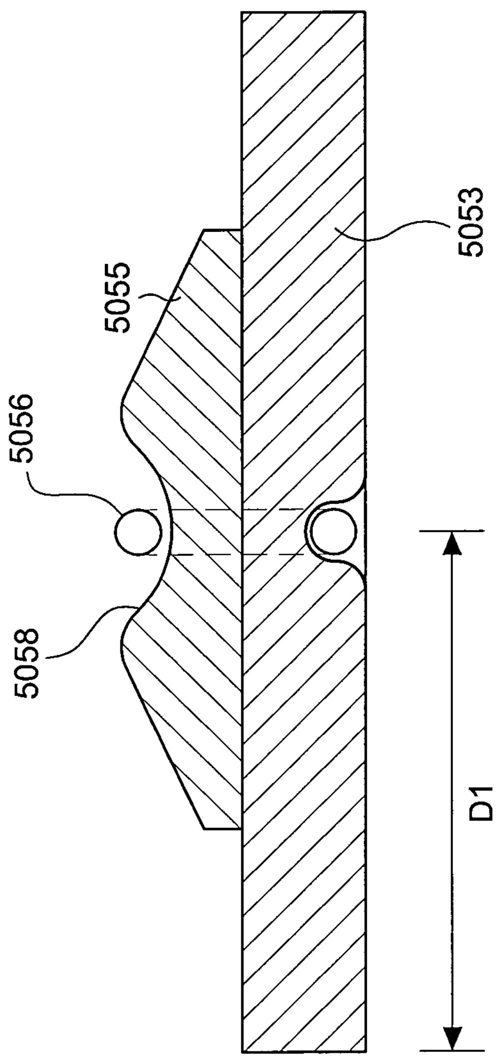


Fig. 19-20

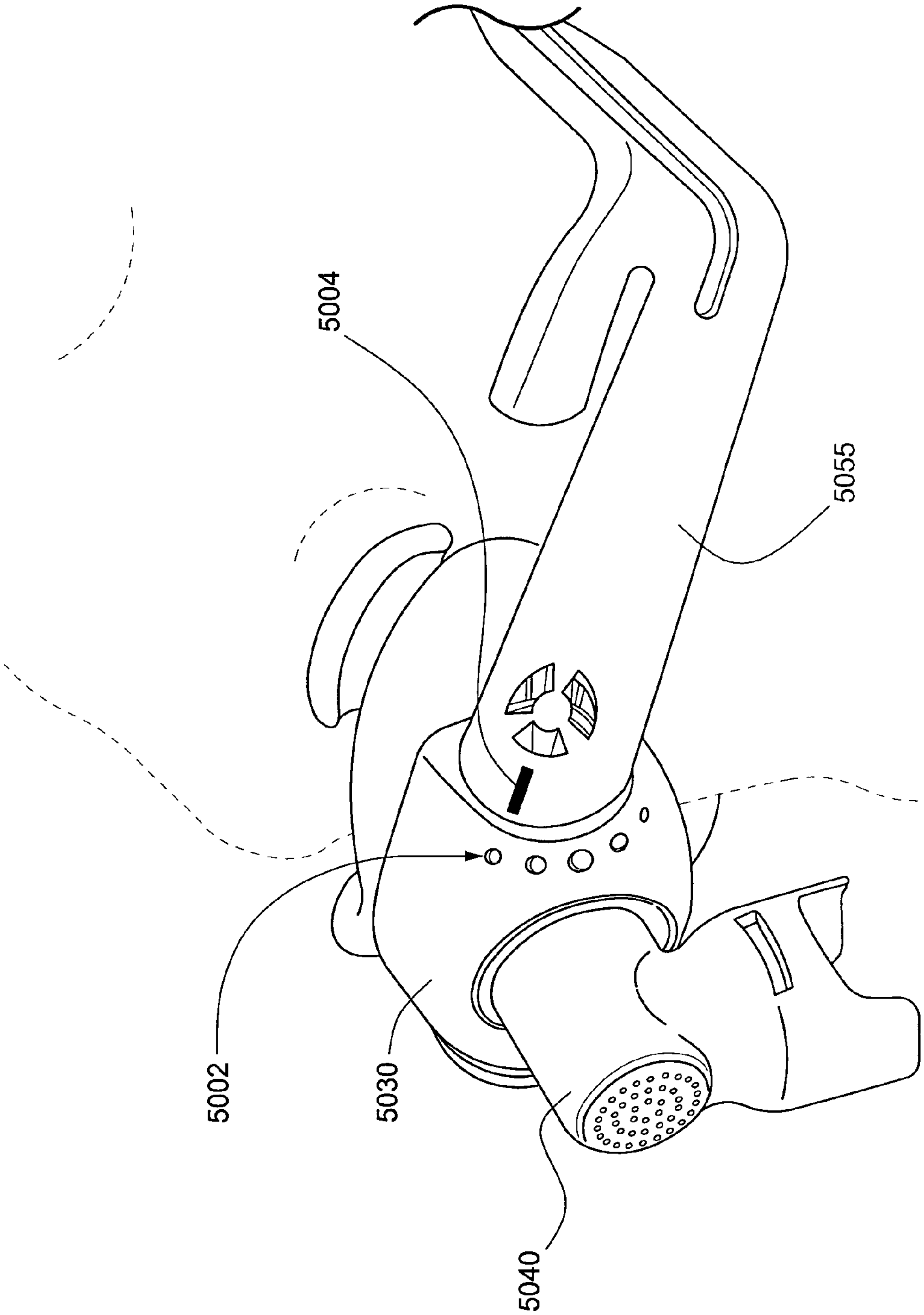
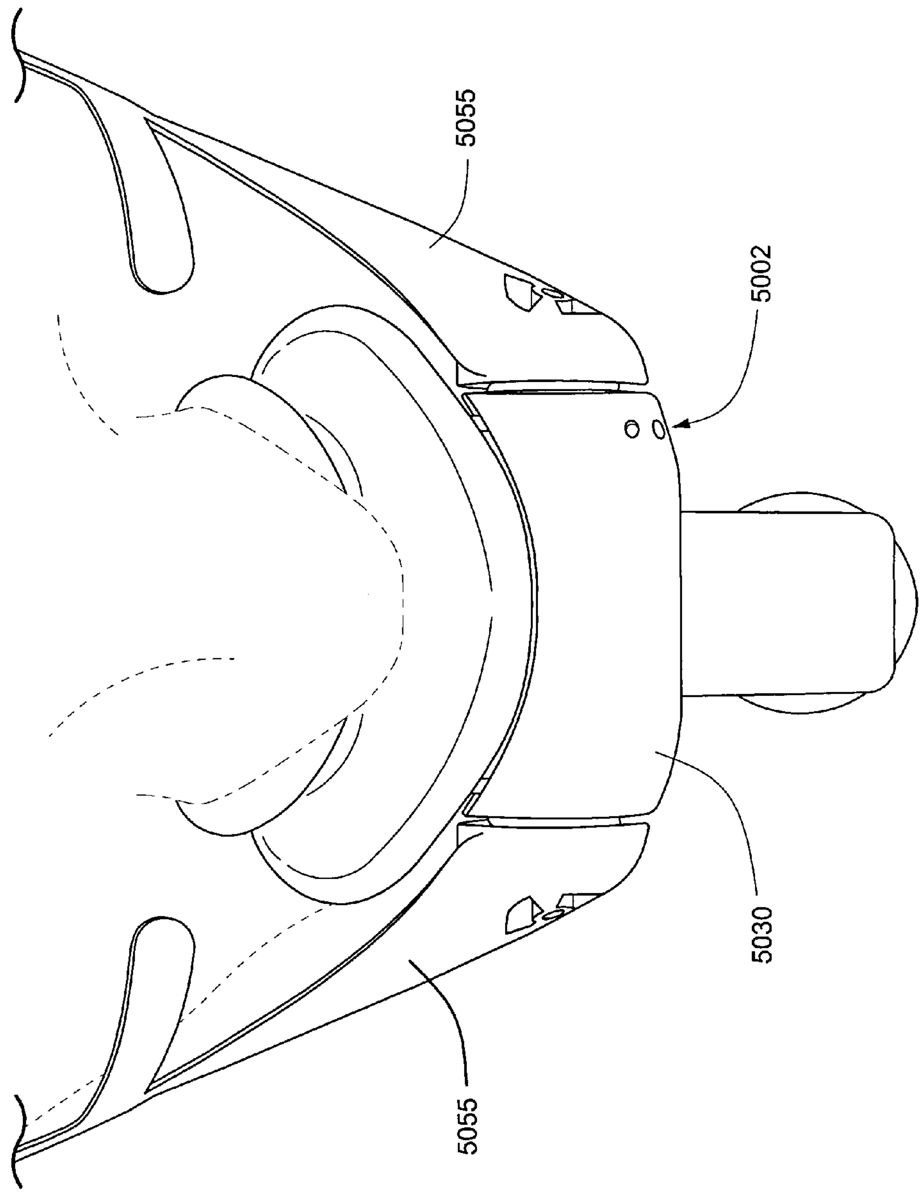


Fig. 19-21-1



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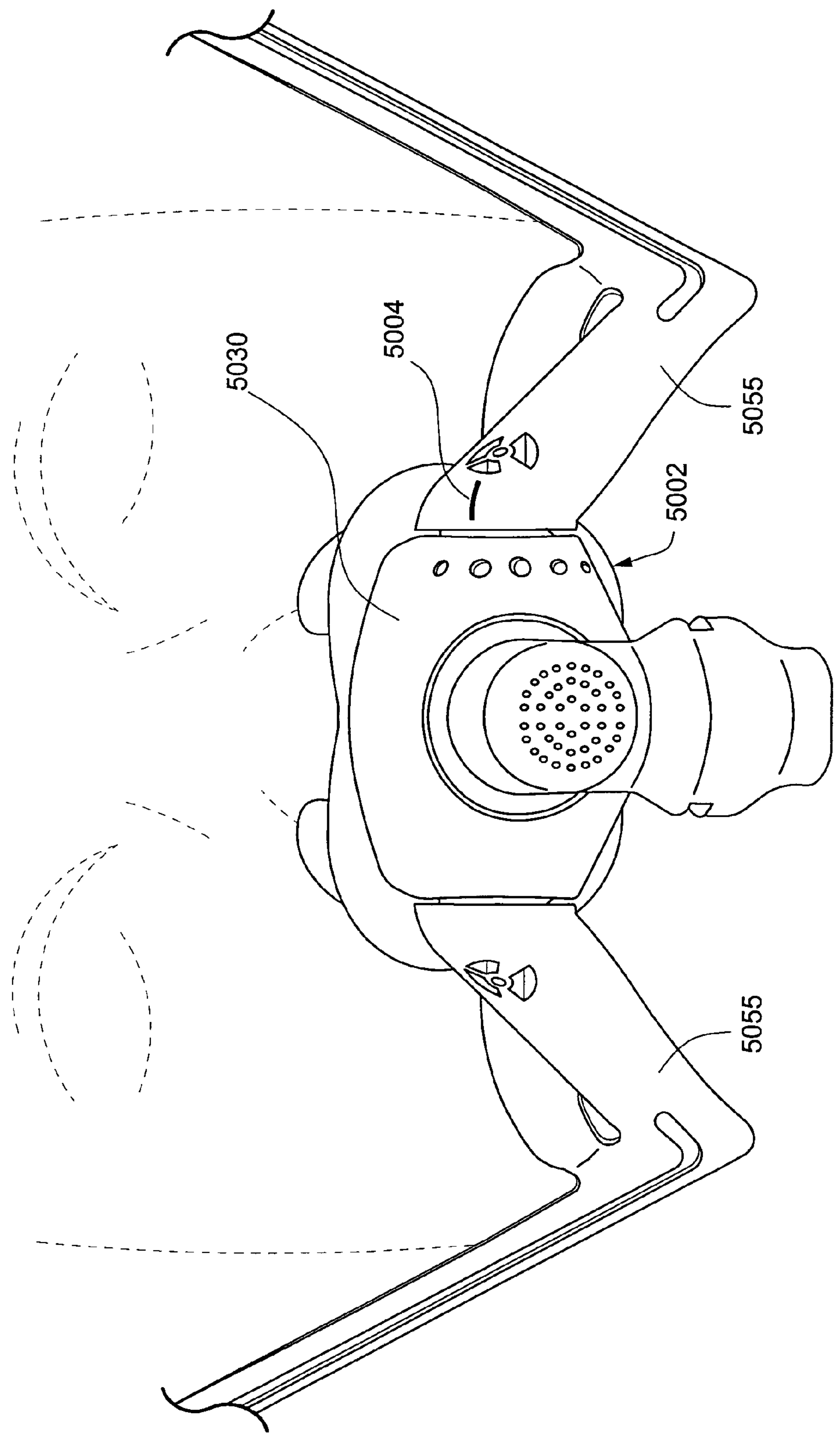

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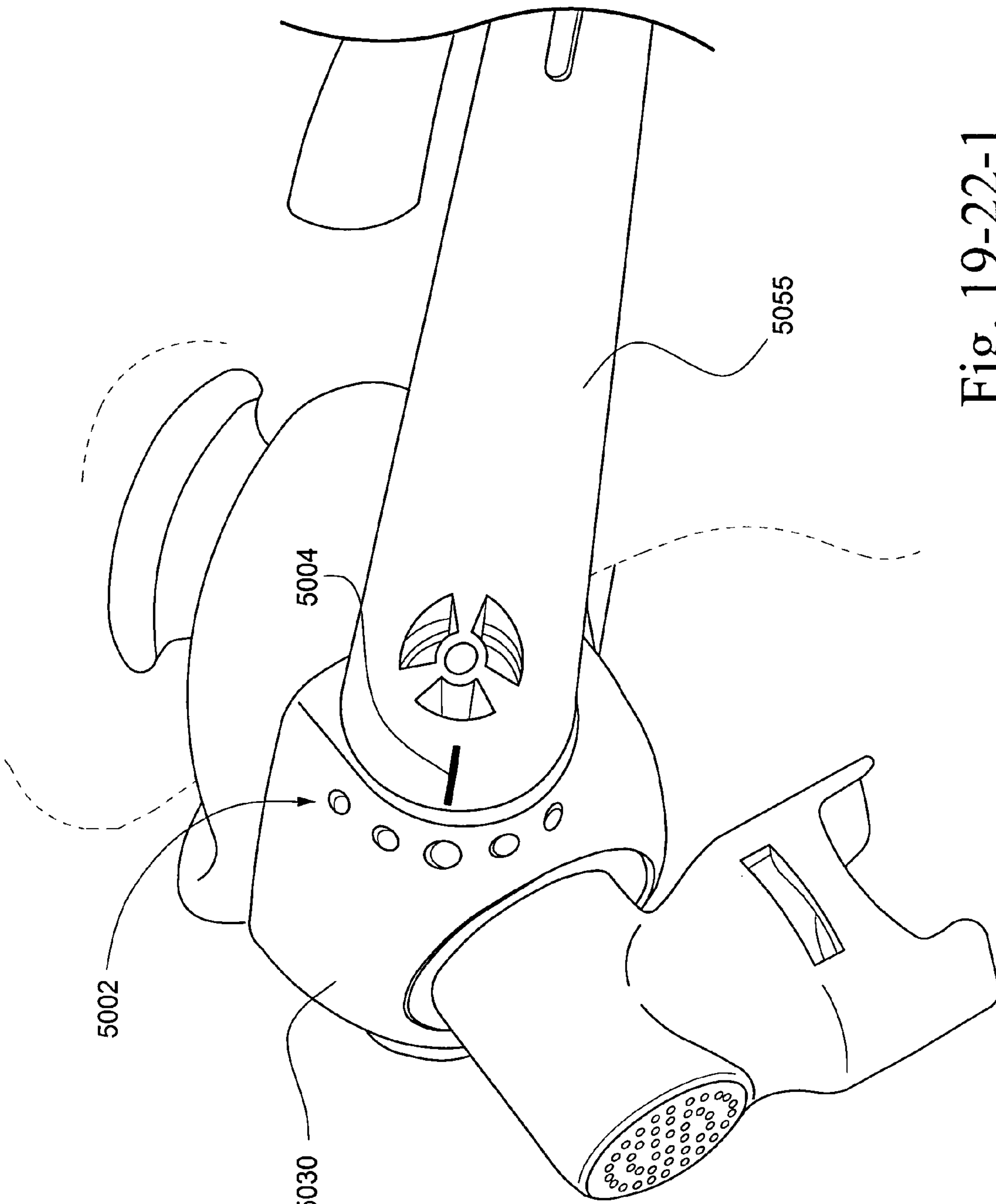

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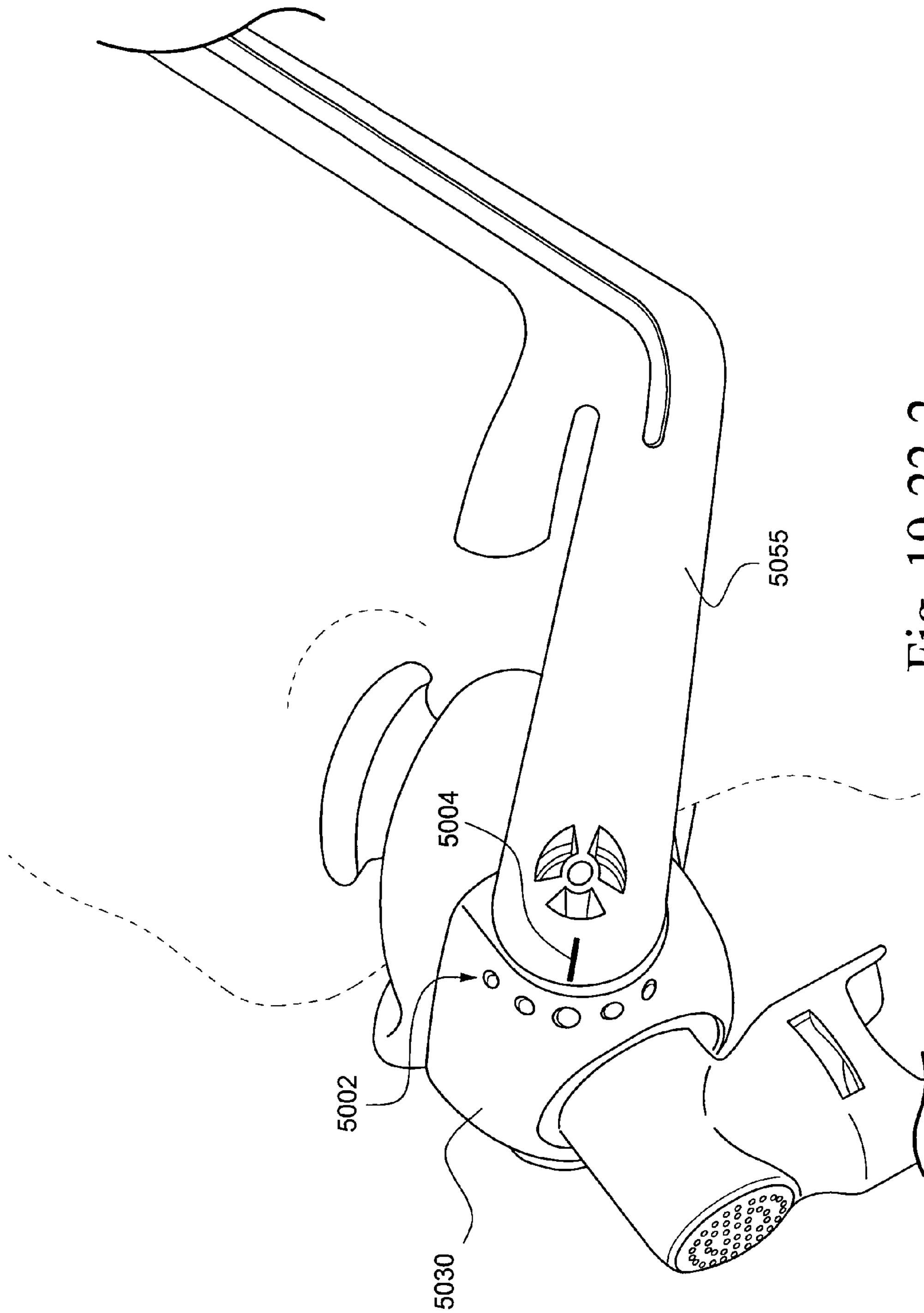

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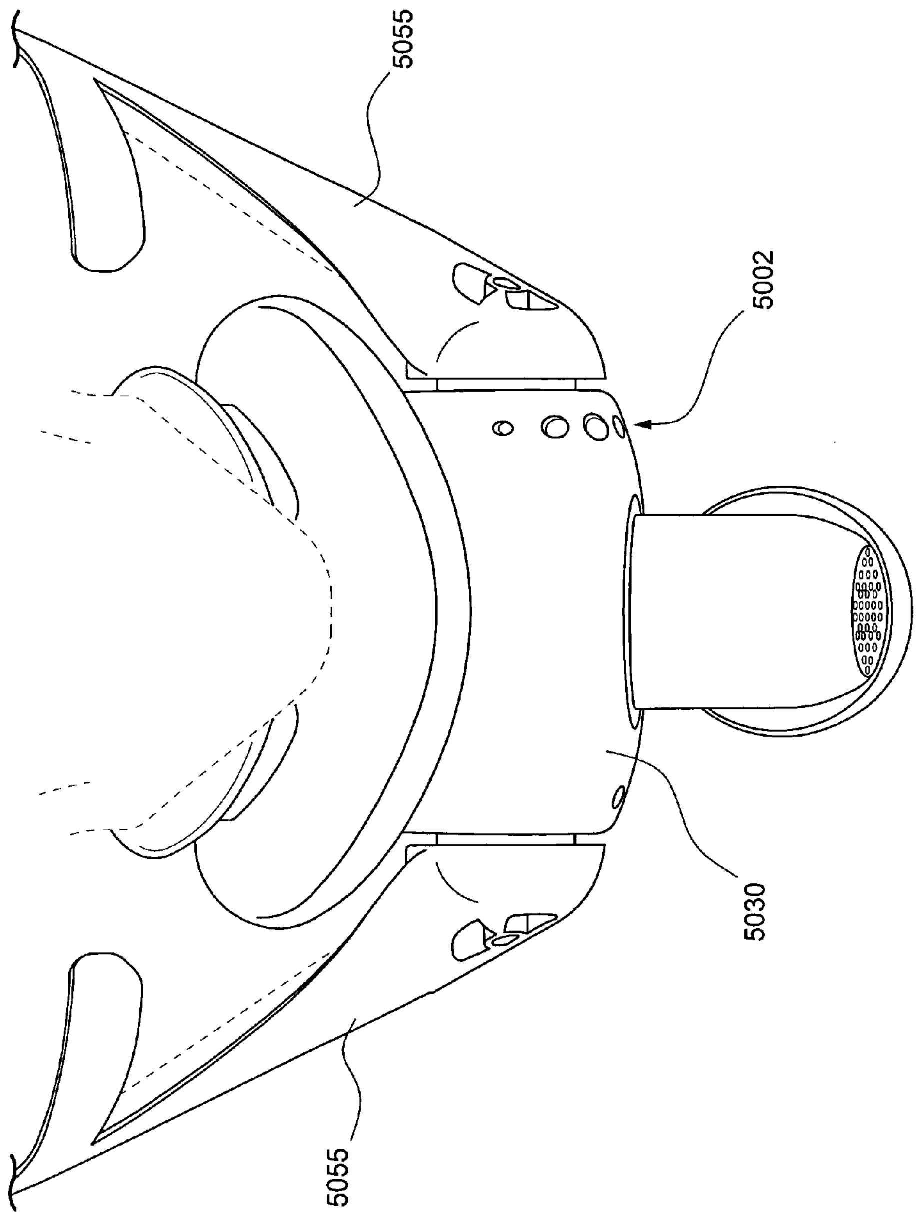

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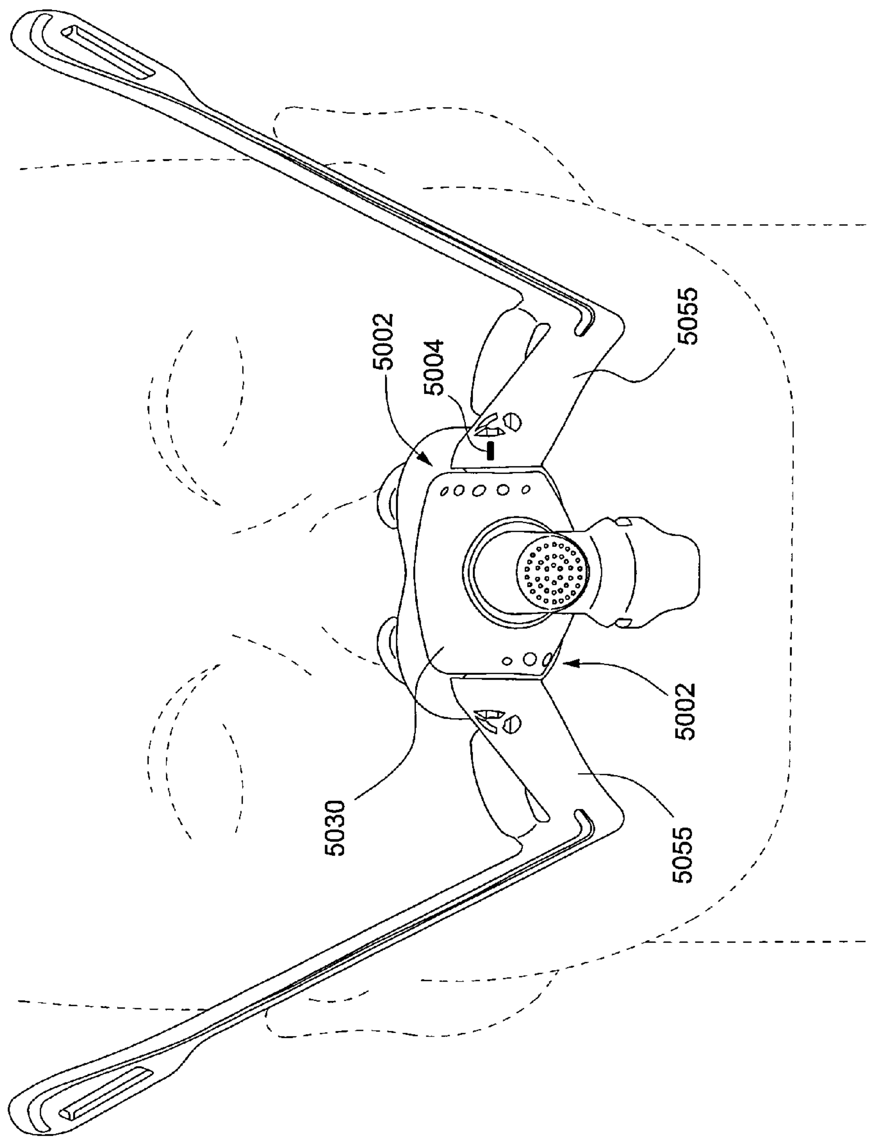

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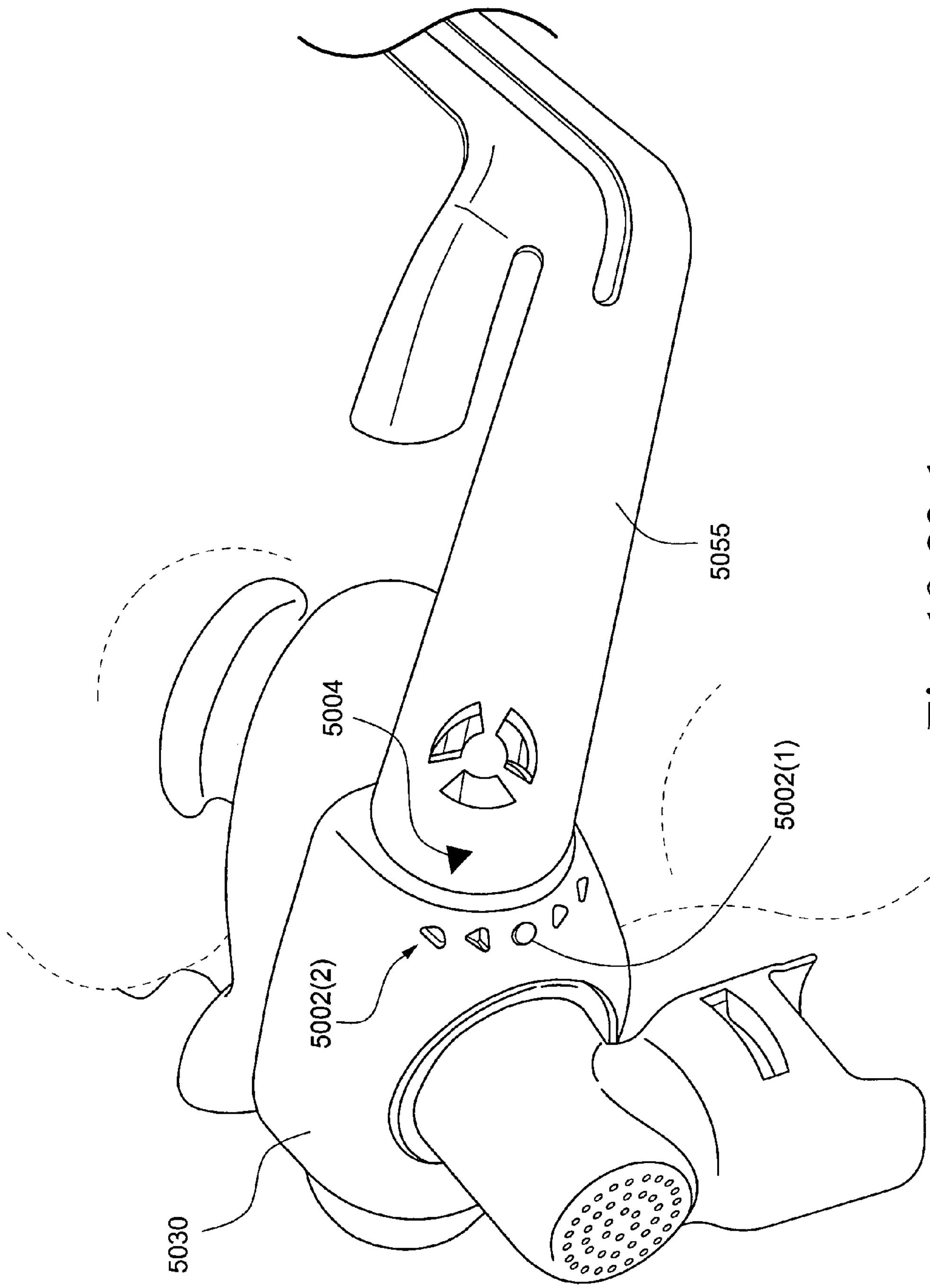

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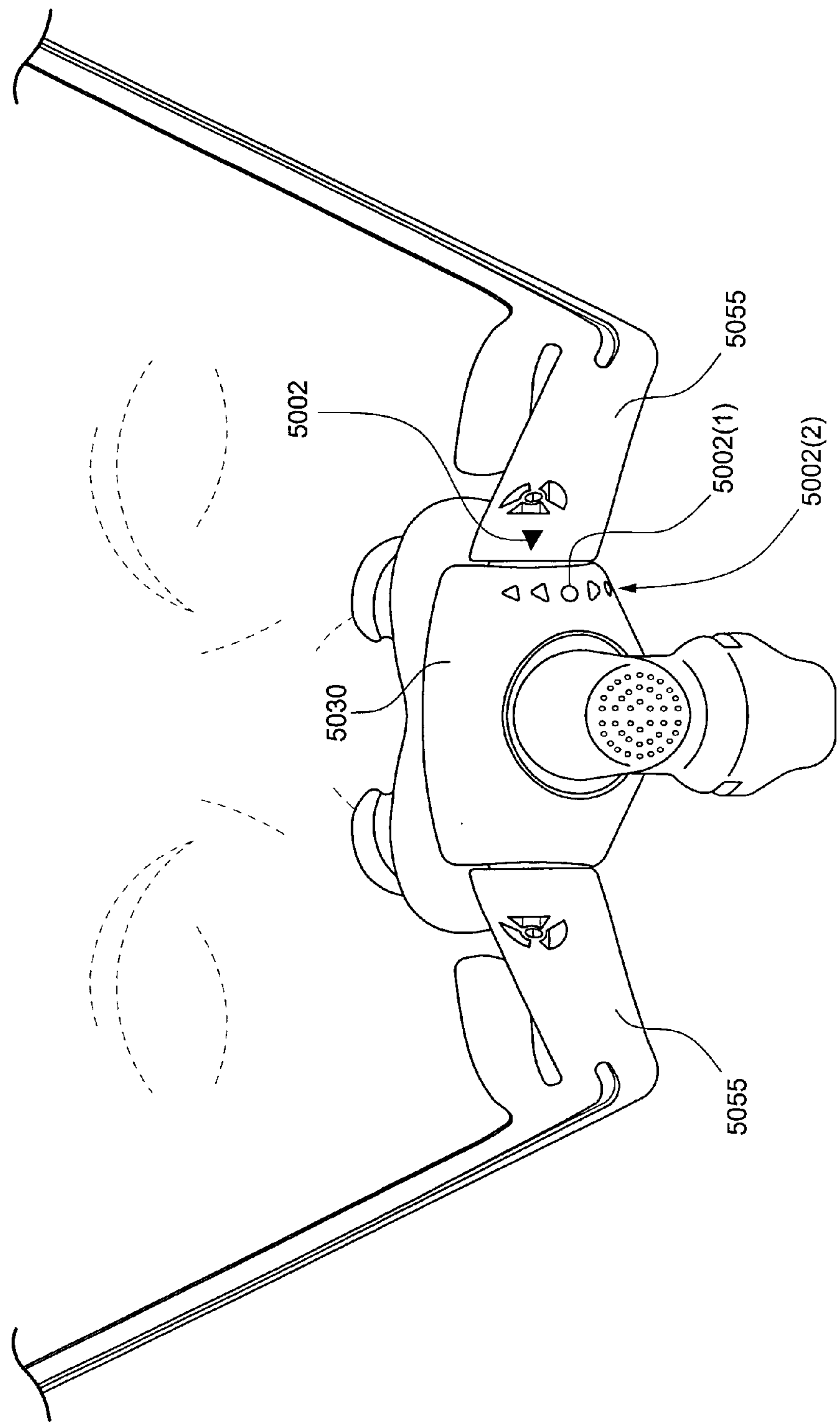

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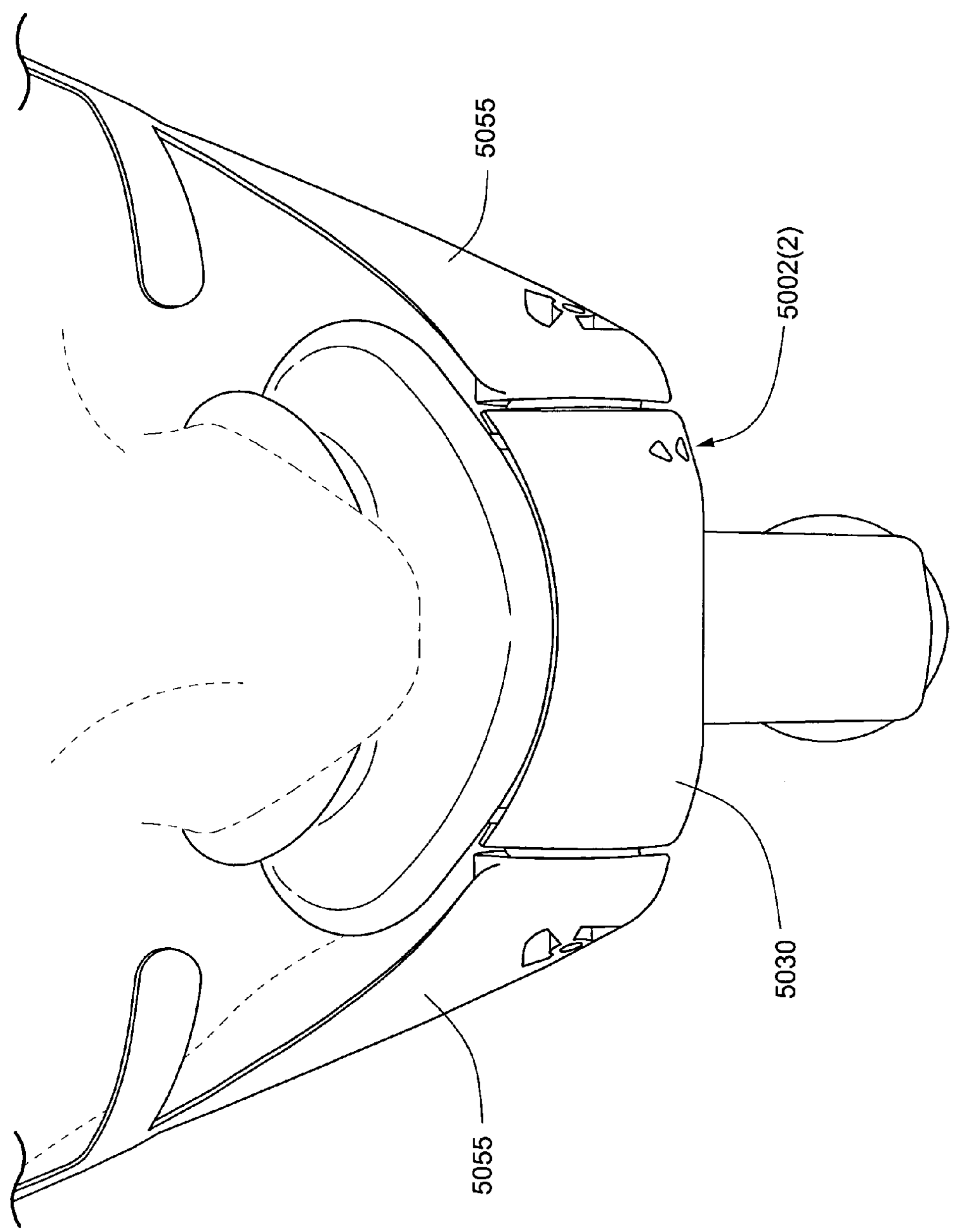


Fig. 19-23-3

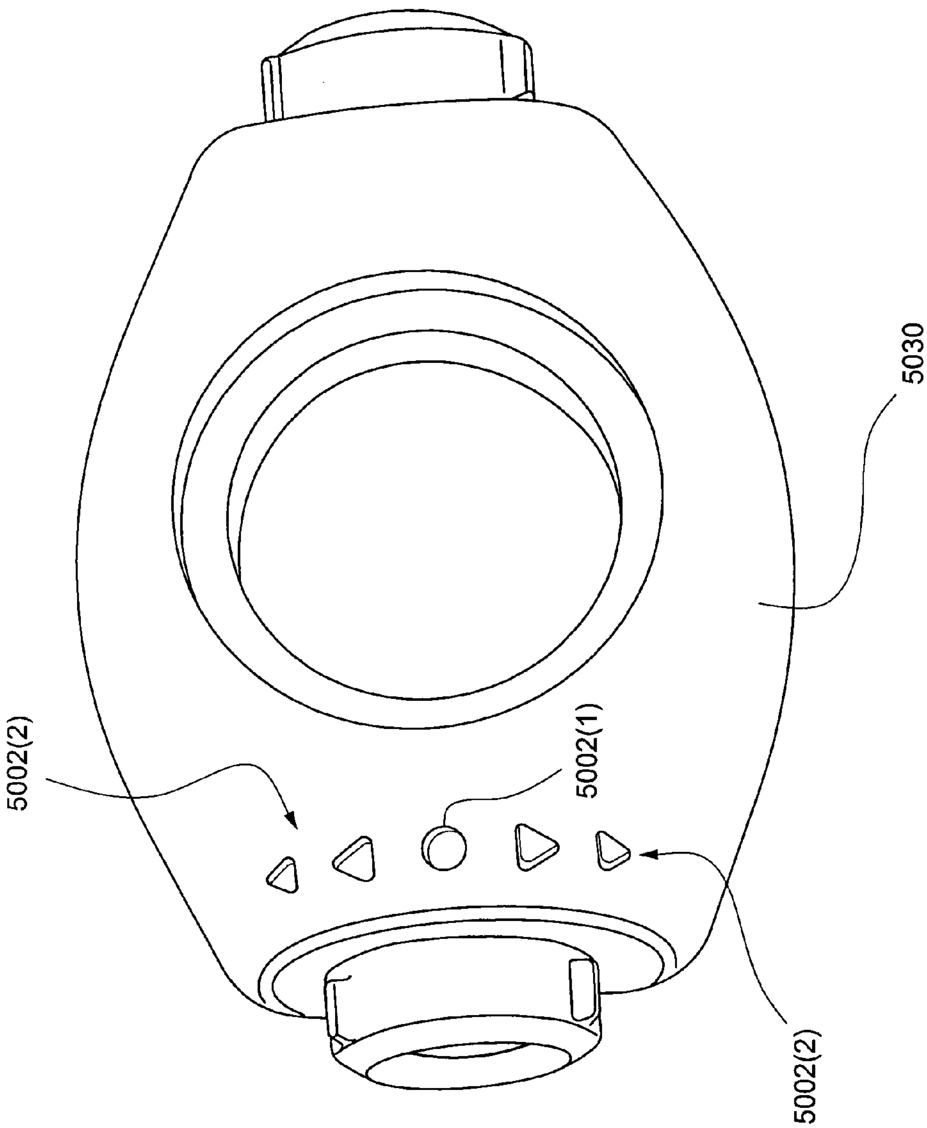


Fig. 19-23-4

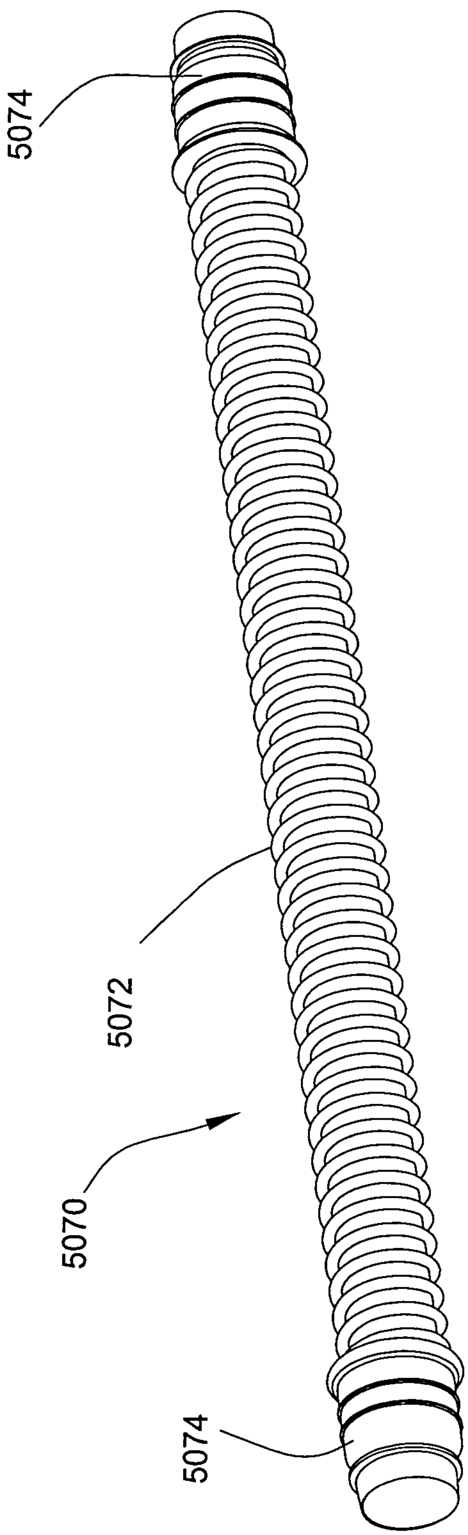
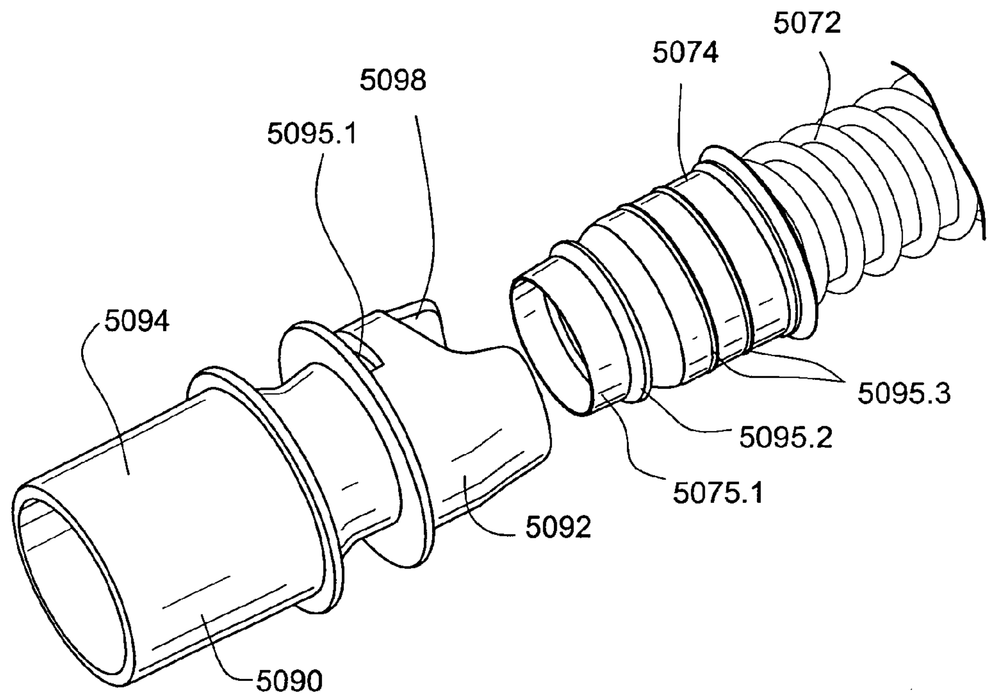


Fig. 20-1



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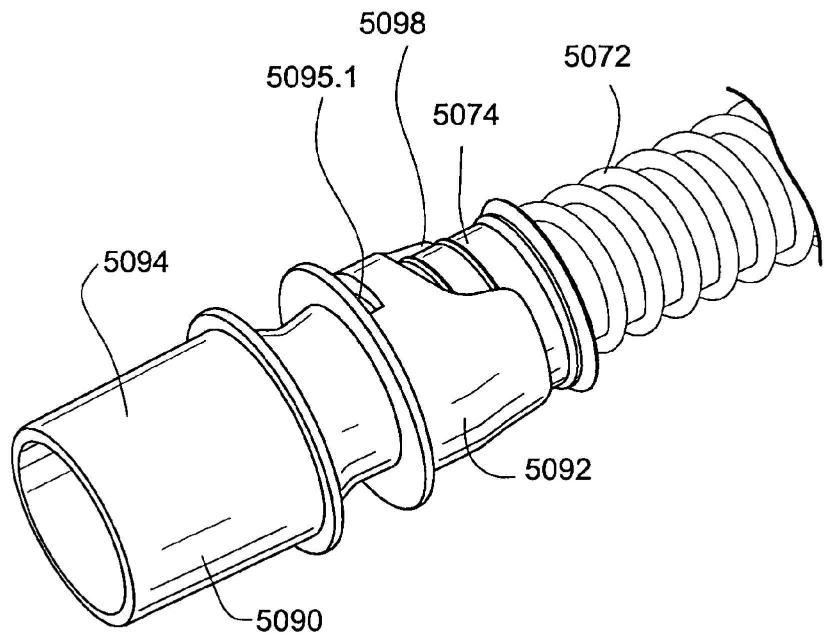

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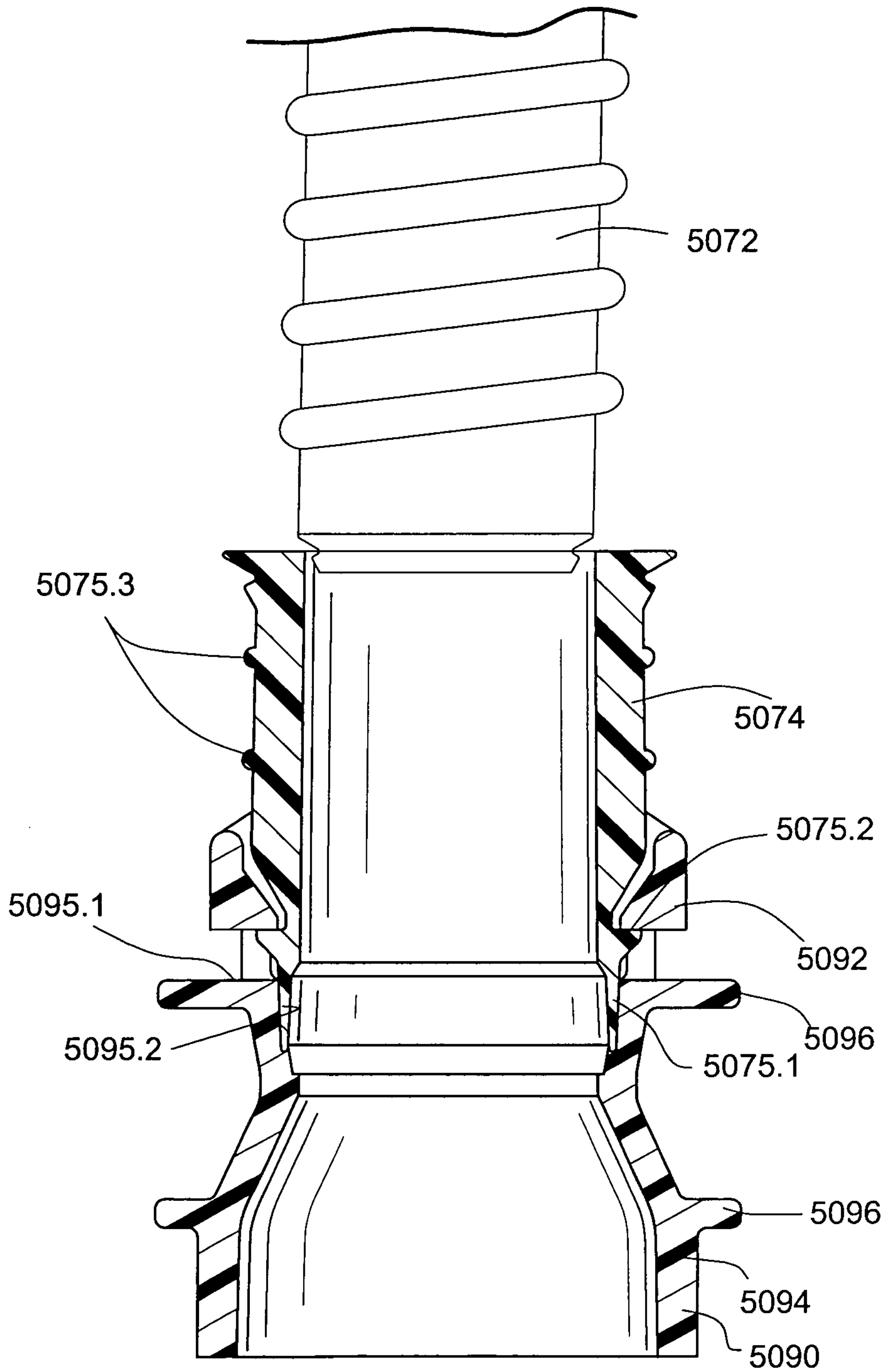
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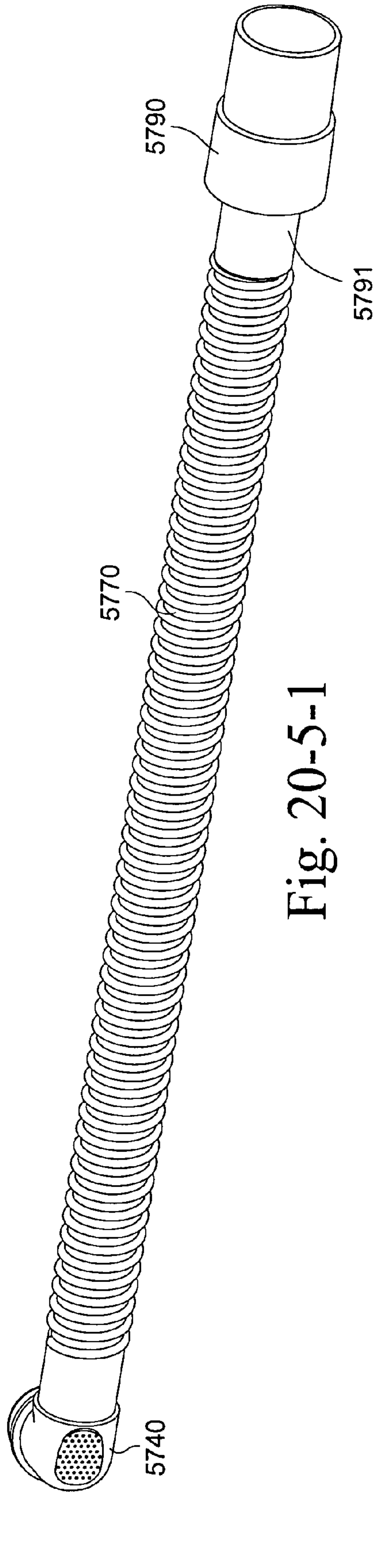
Fig. 20-4



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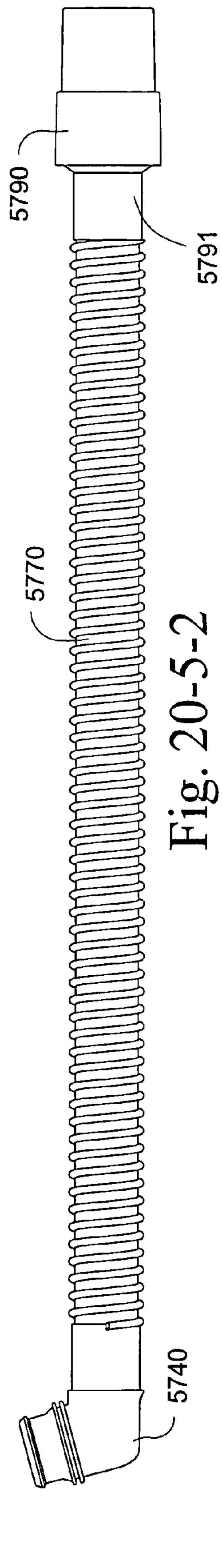

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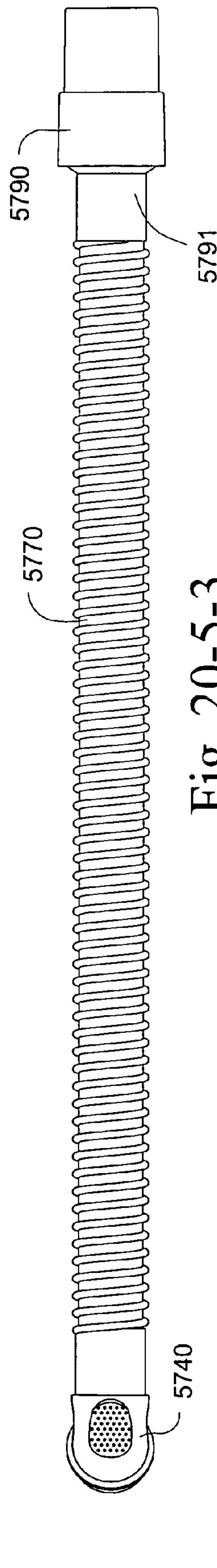

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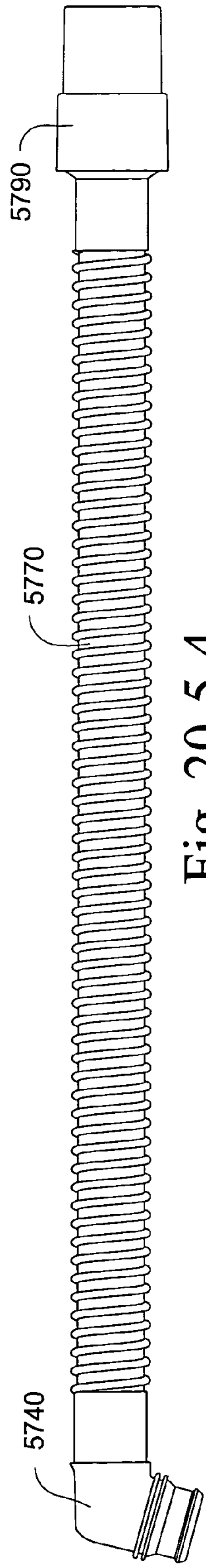

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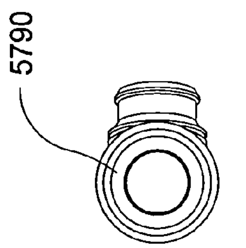

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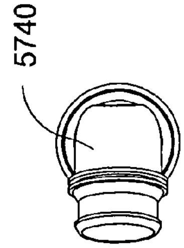

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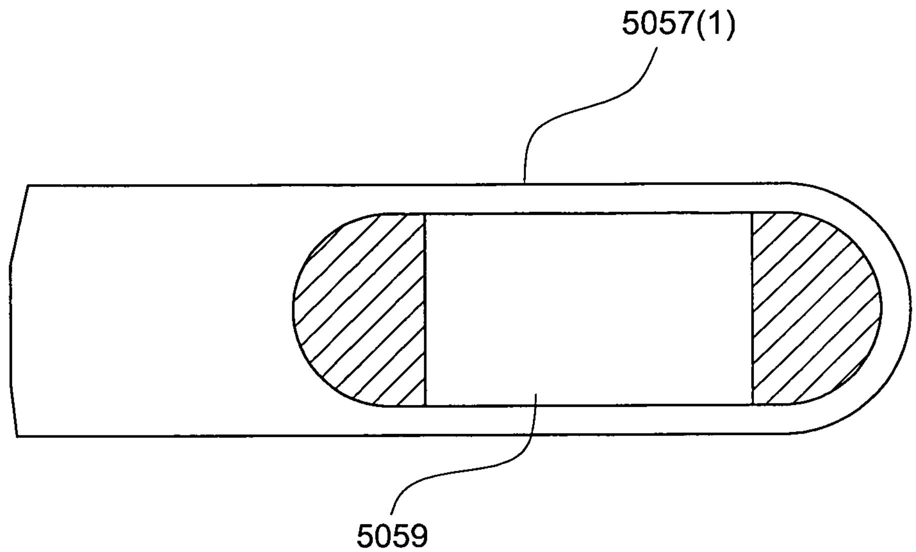

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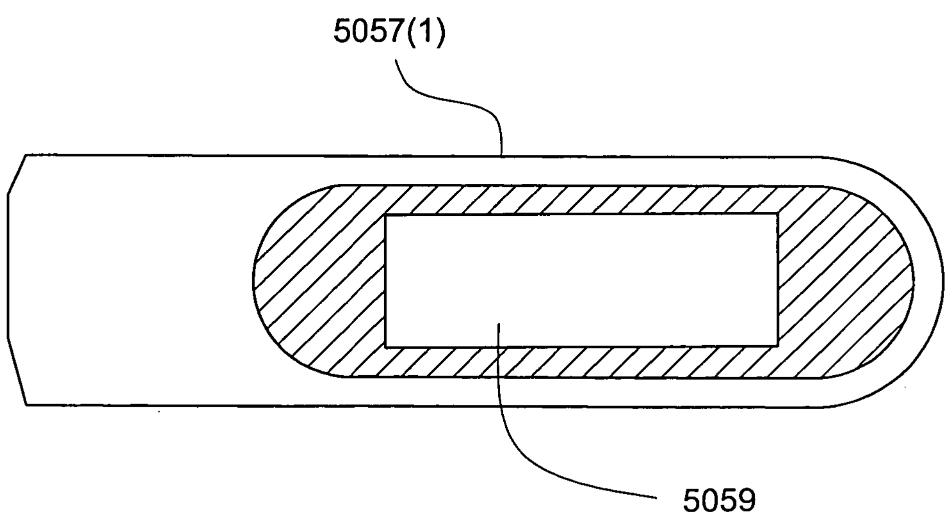

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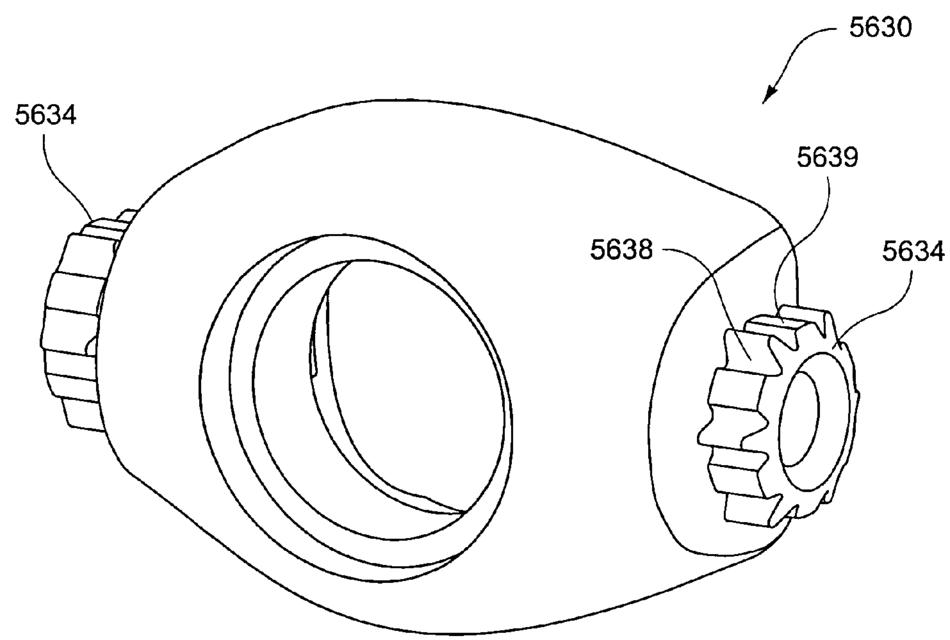


Fig. 22-1-1

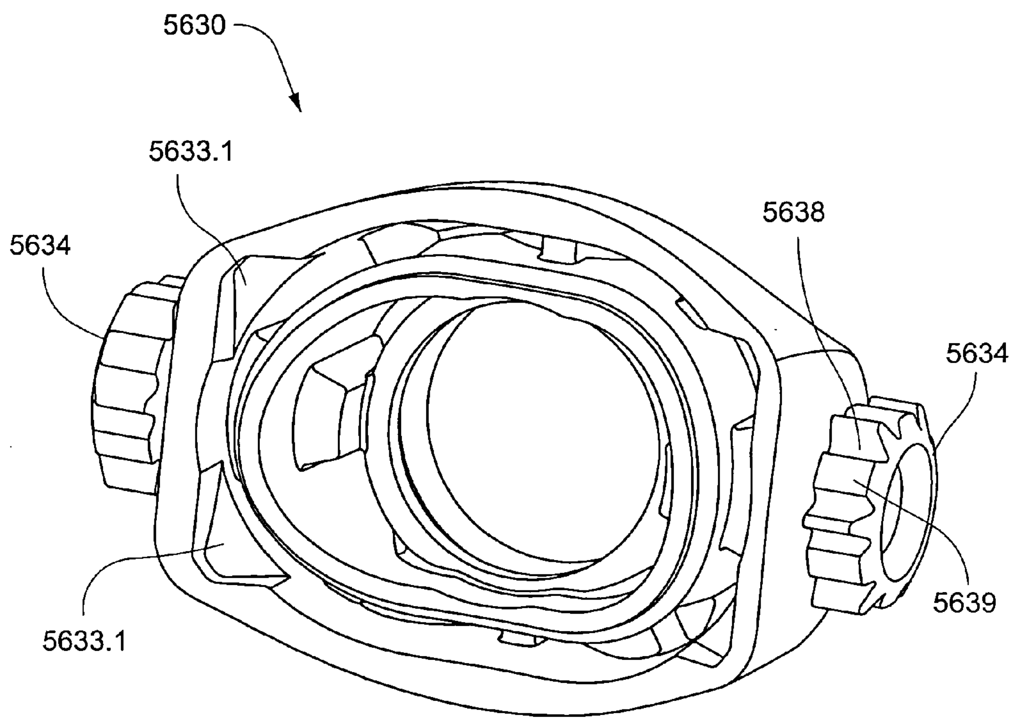
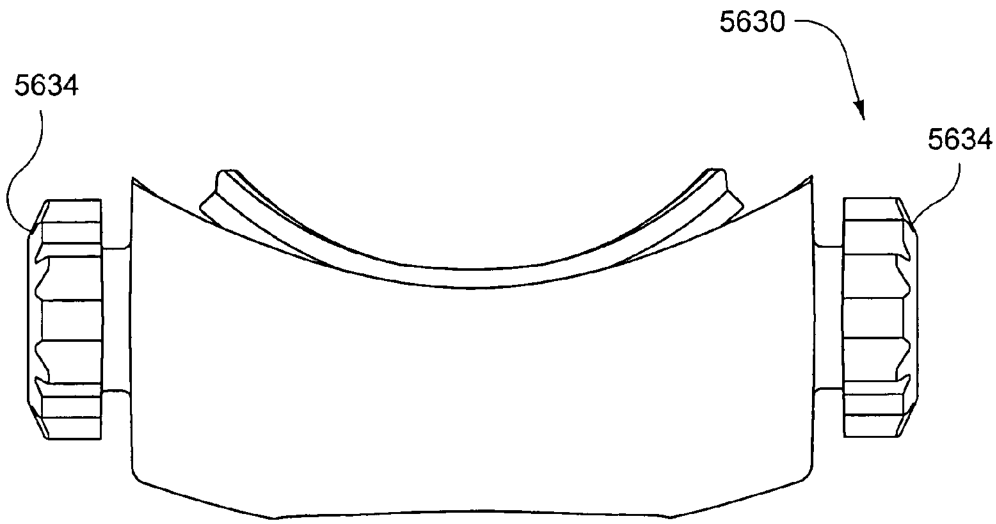


Fig. 22-1-2



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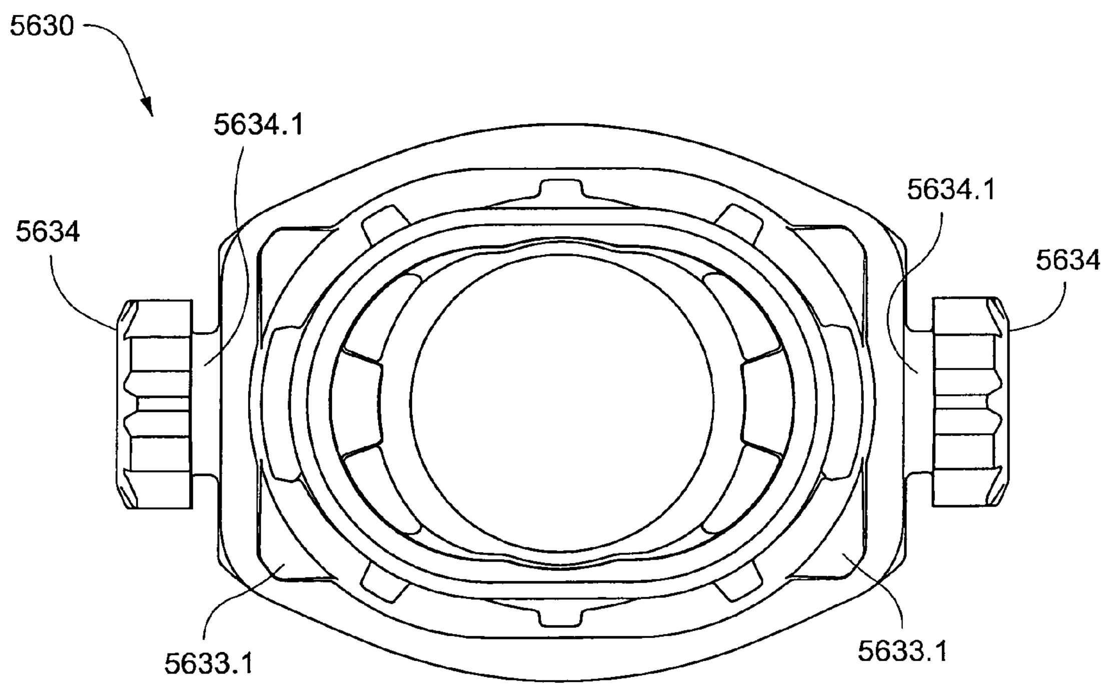

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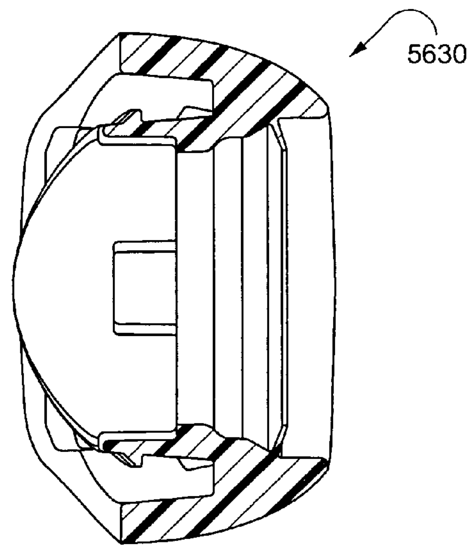

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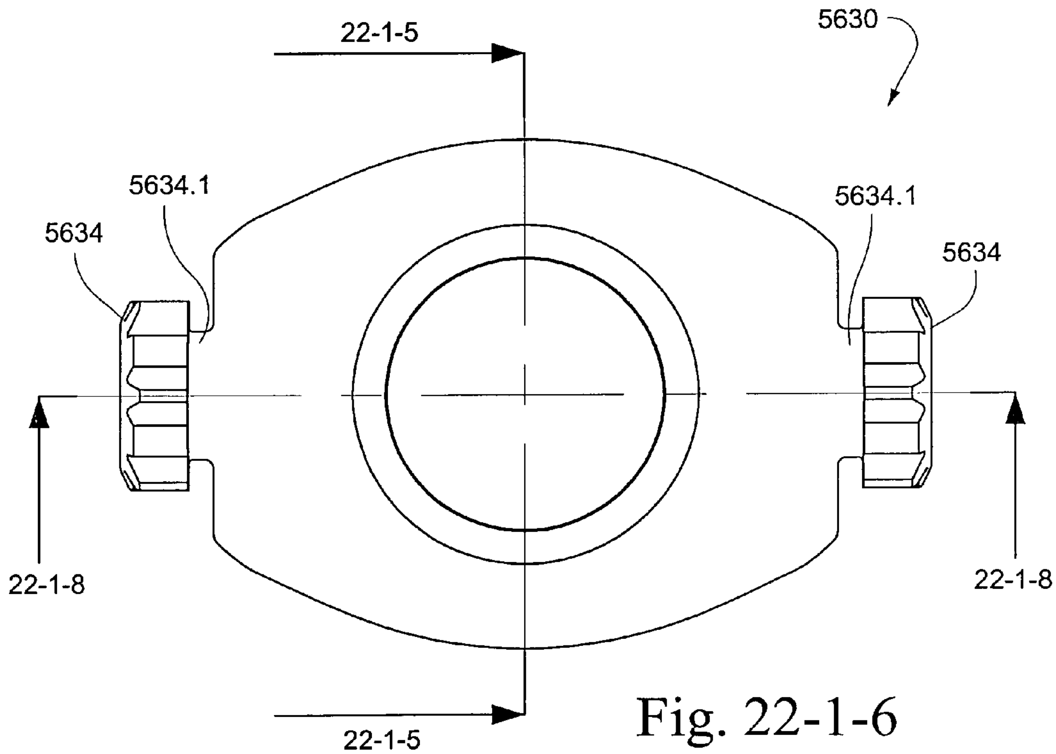

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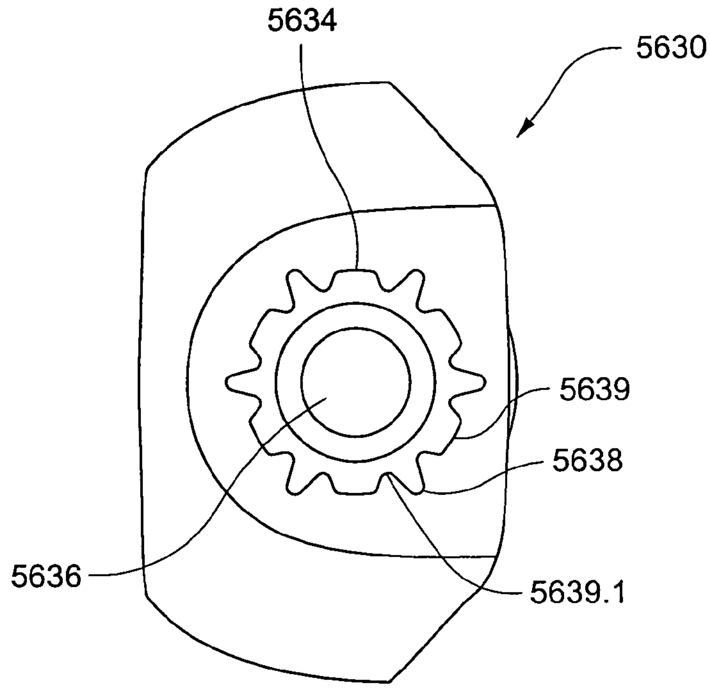

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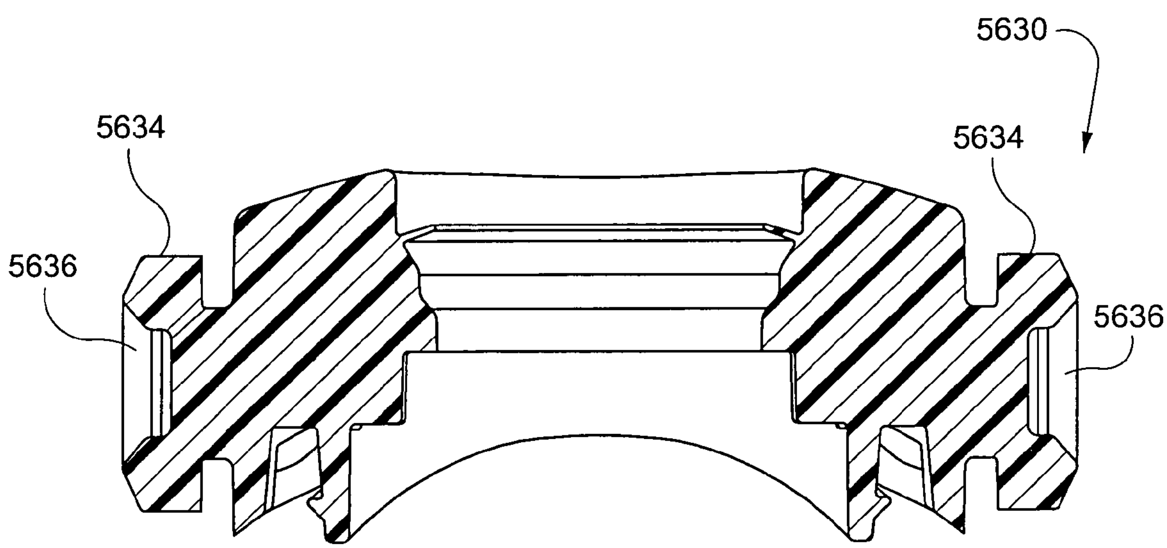

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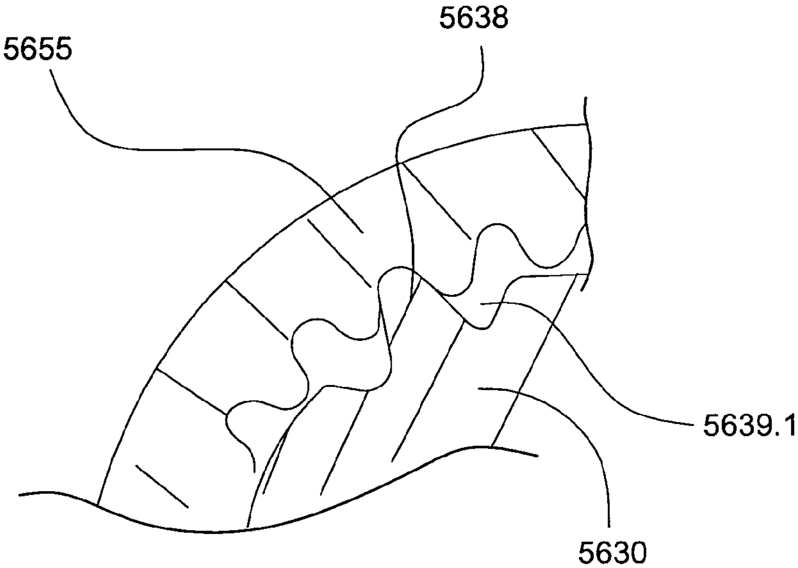

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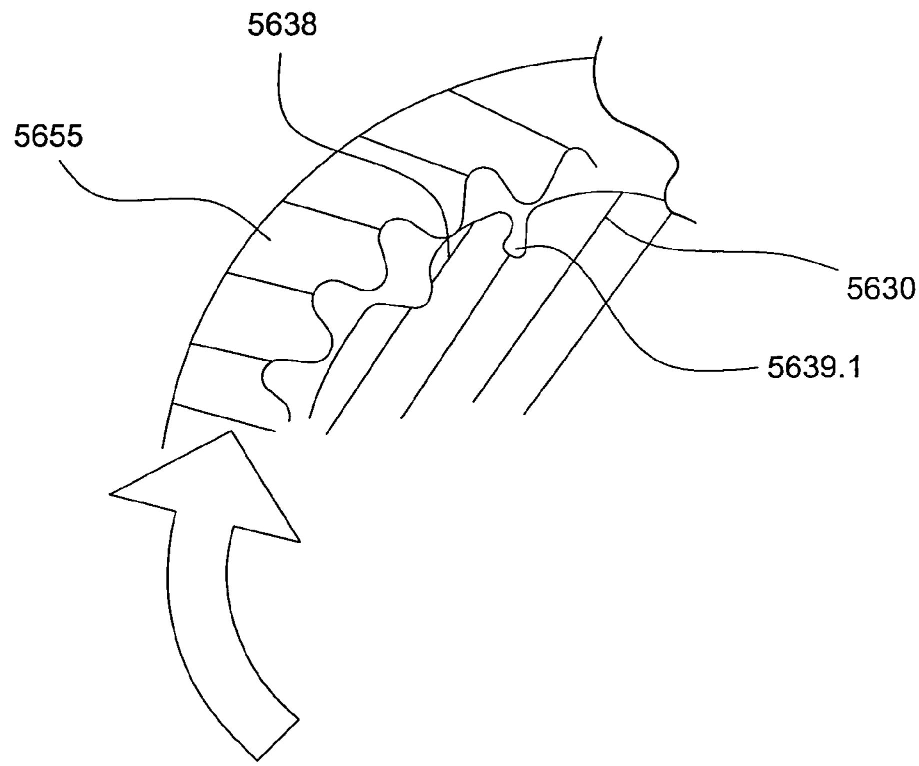

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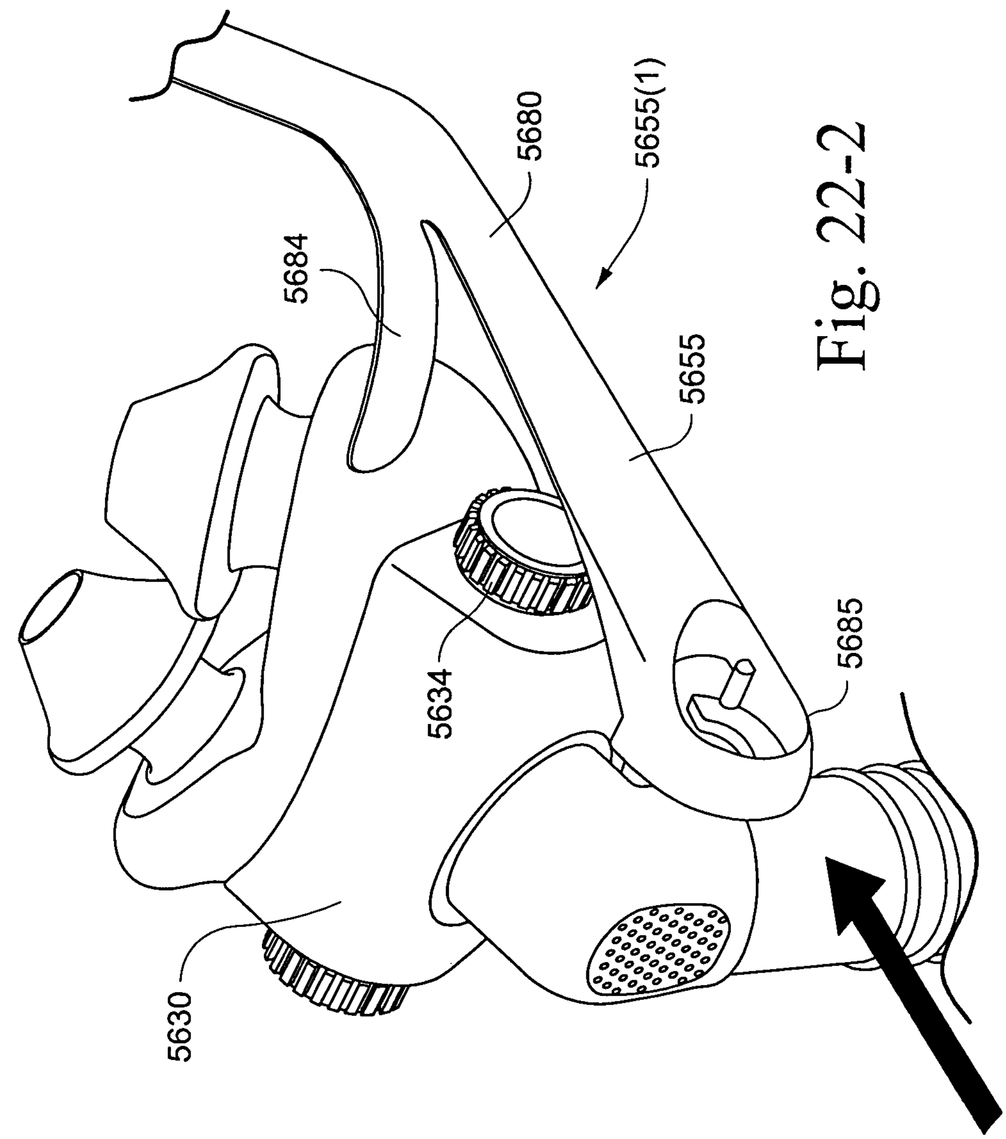
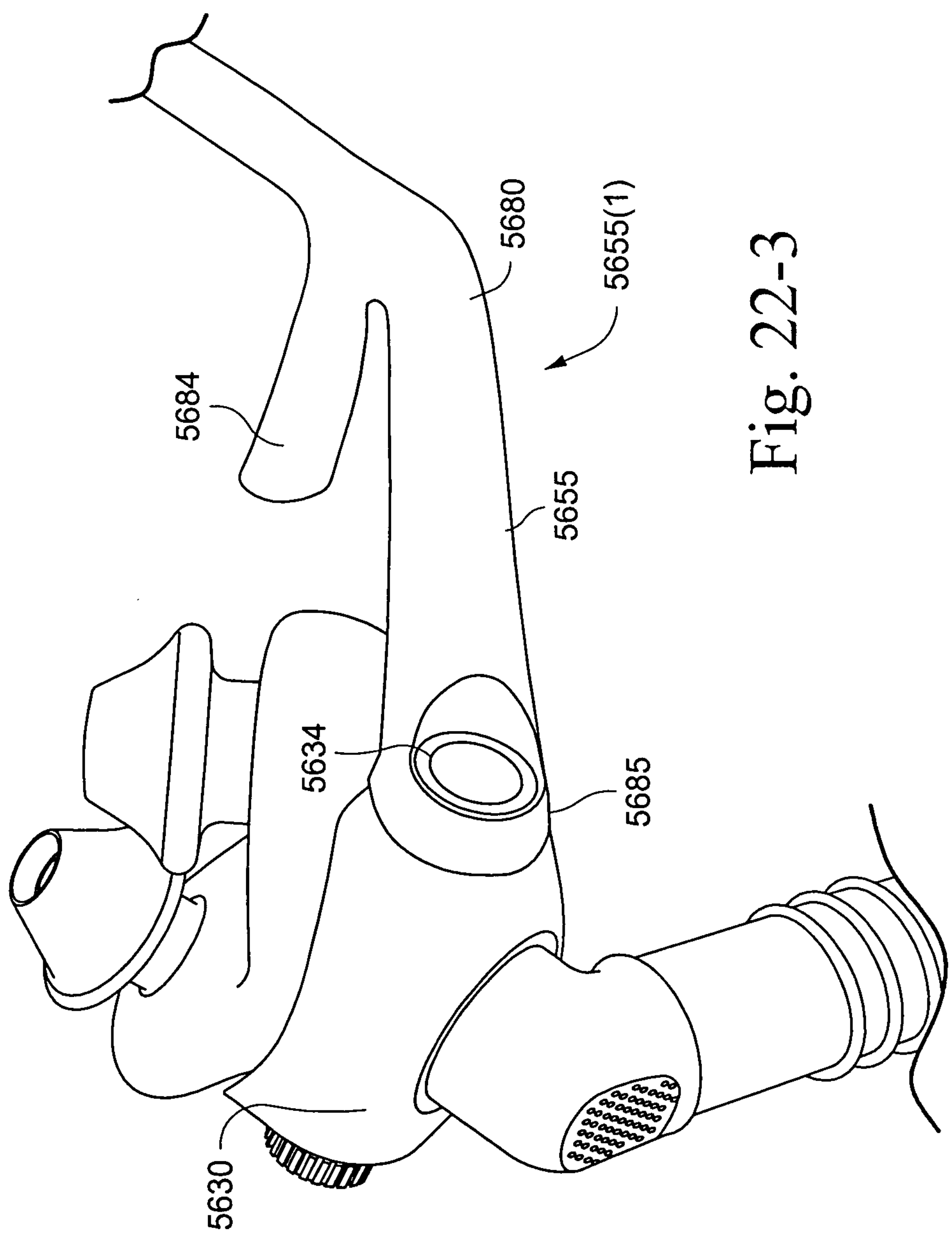


Fig. 22-2



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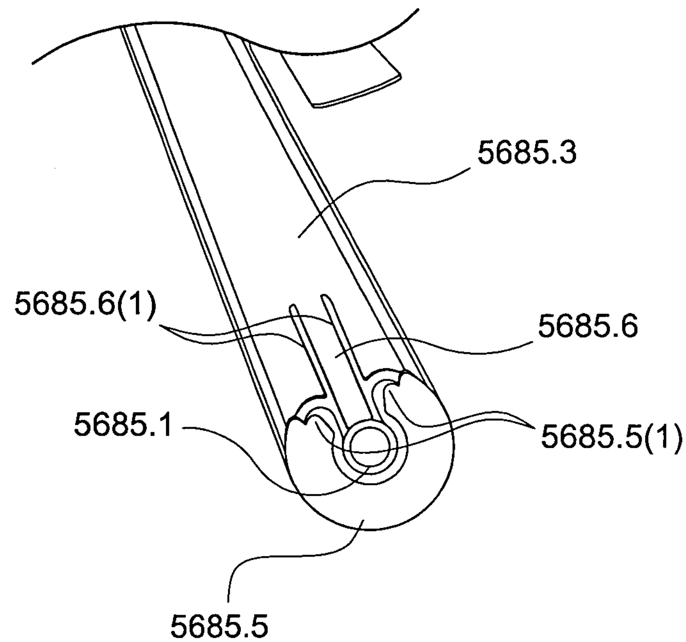

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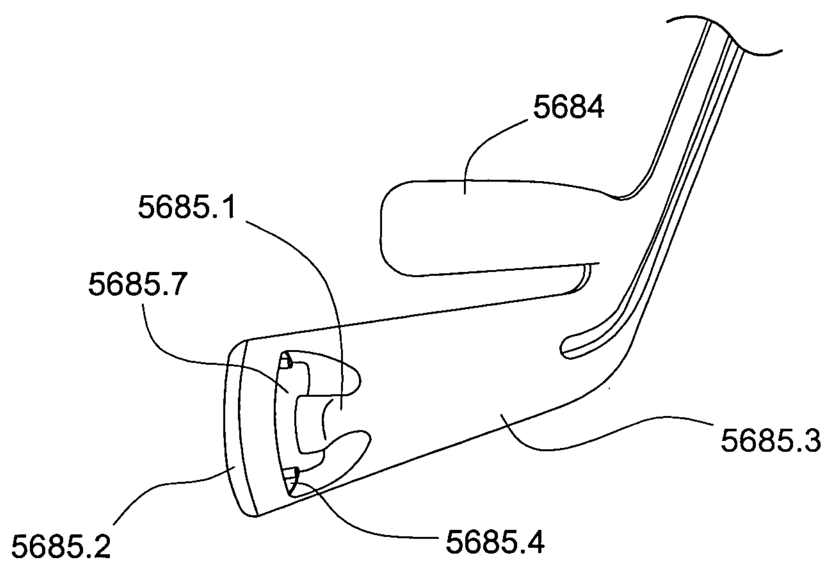

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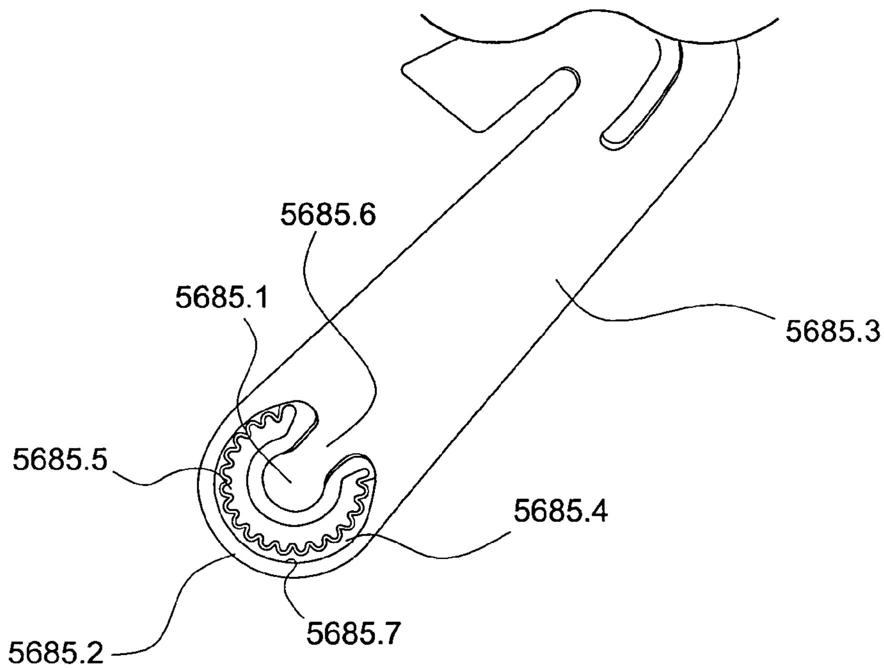

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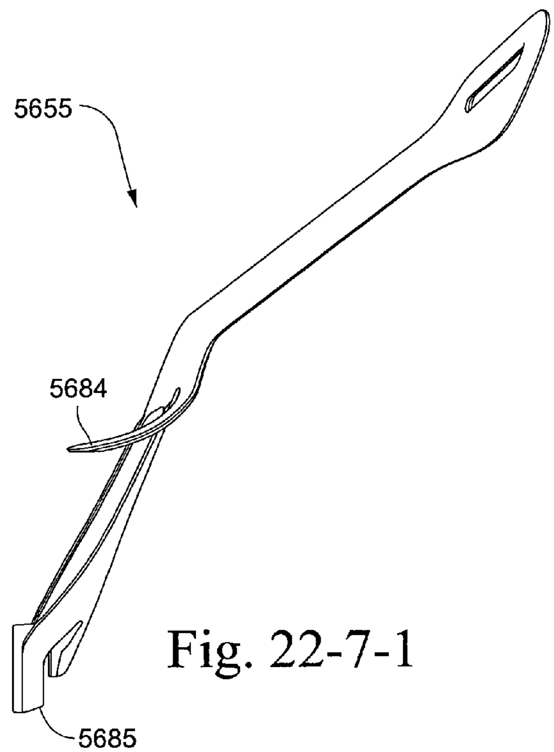

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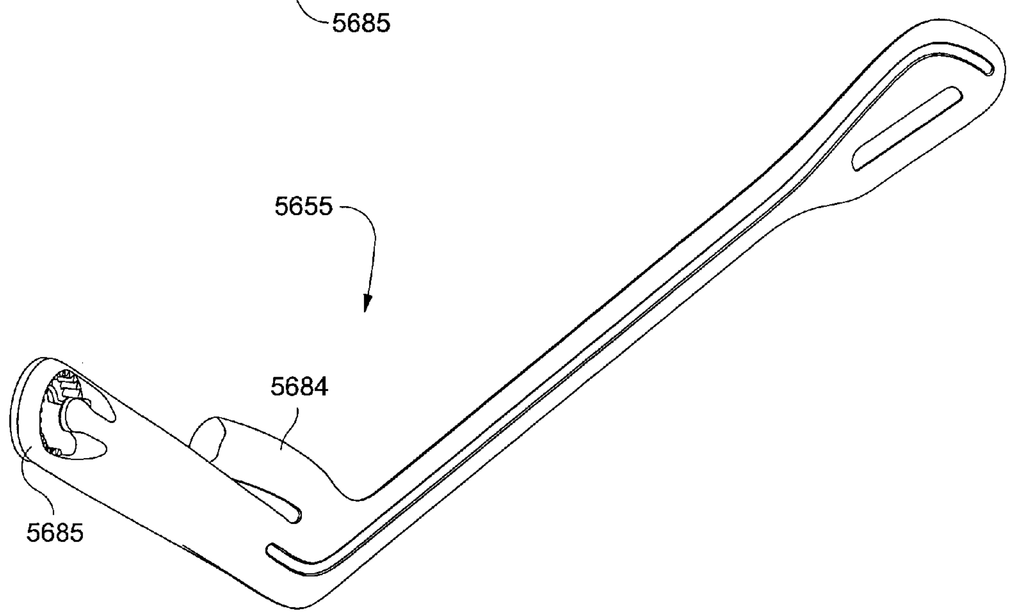

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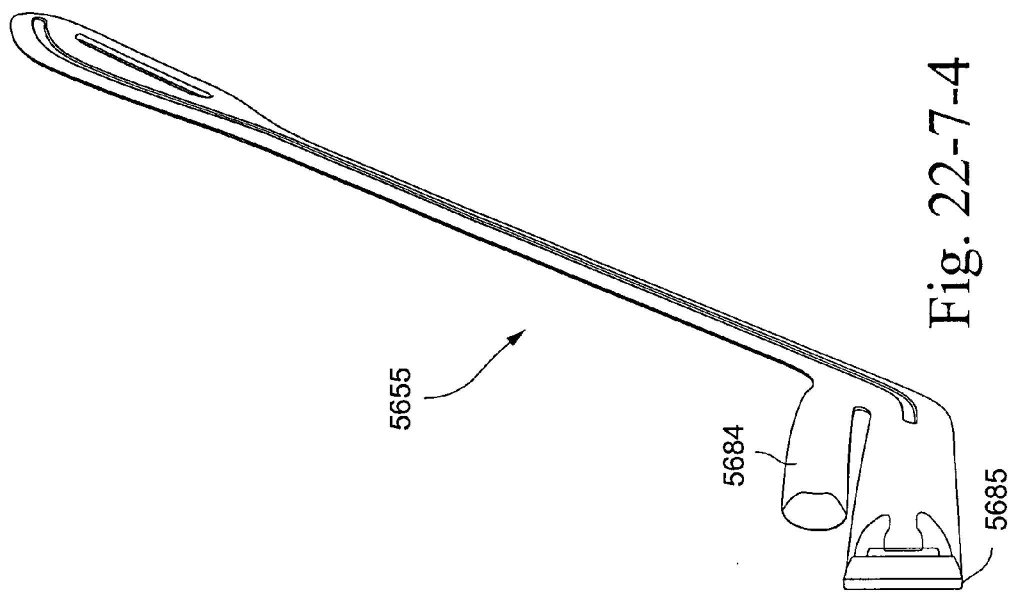

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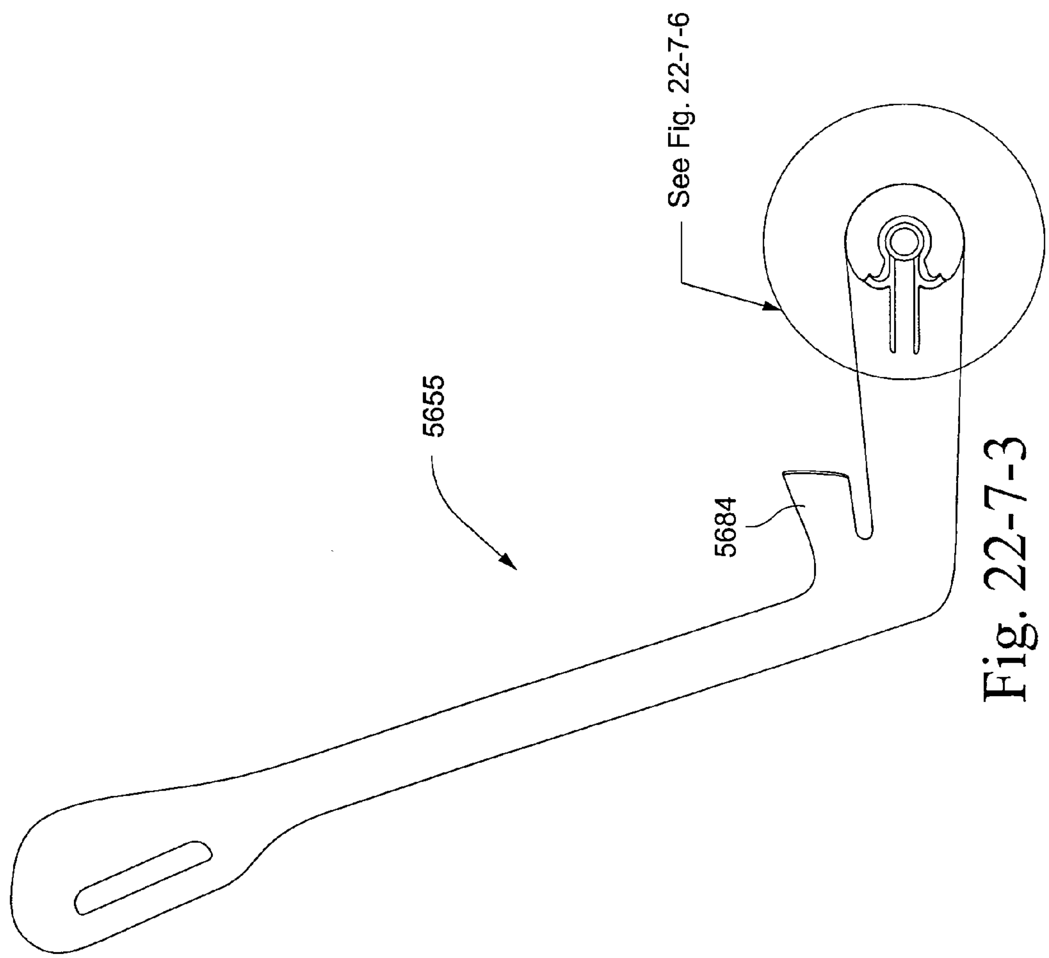

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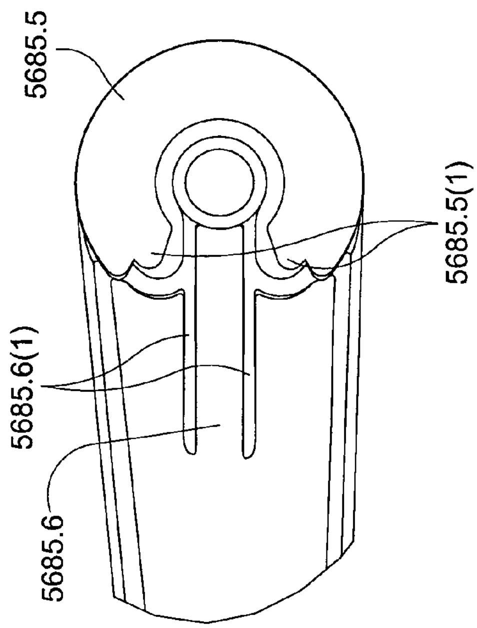

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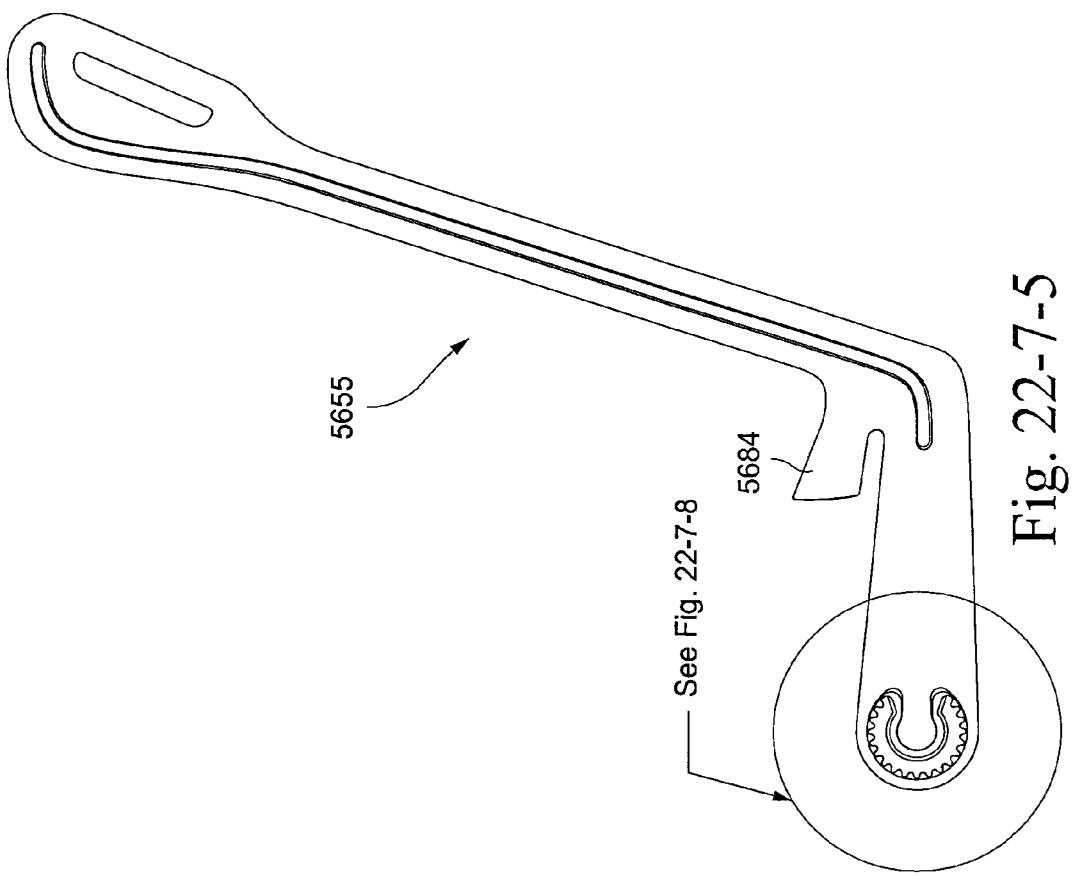

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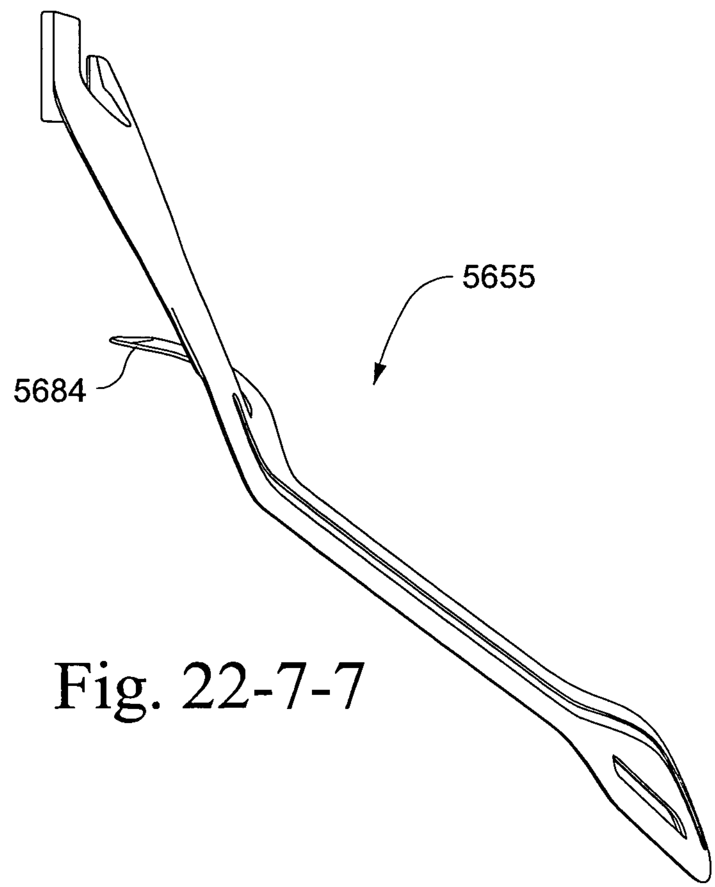

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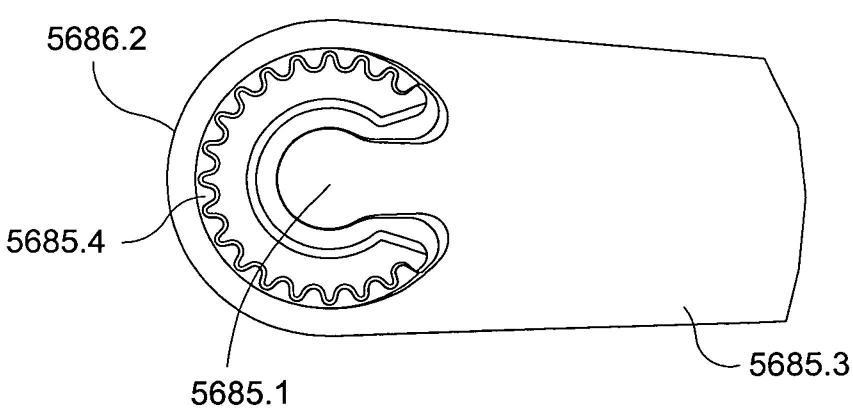

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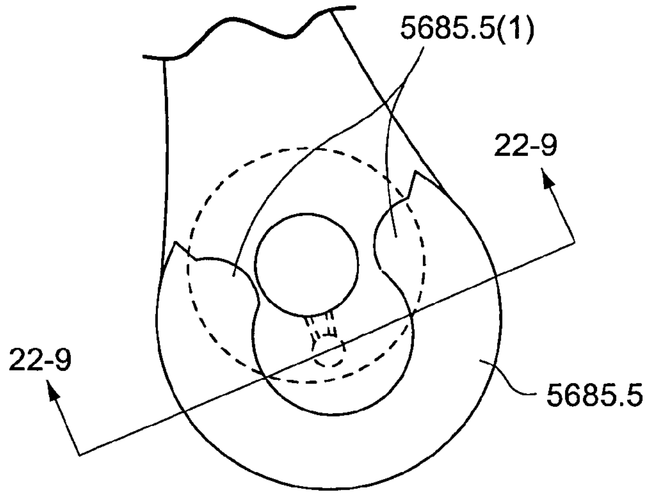

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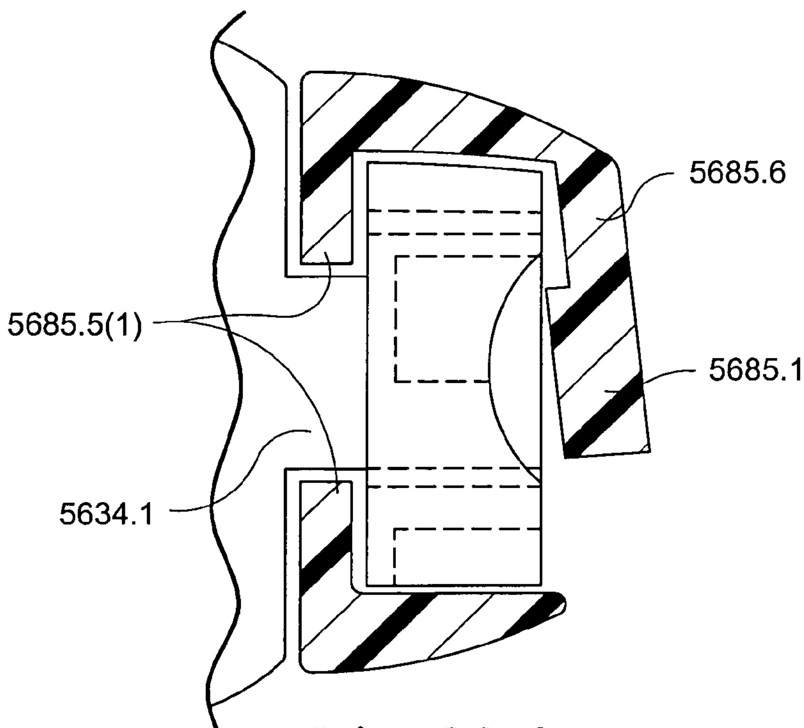

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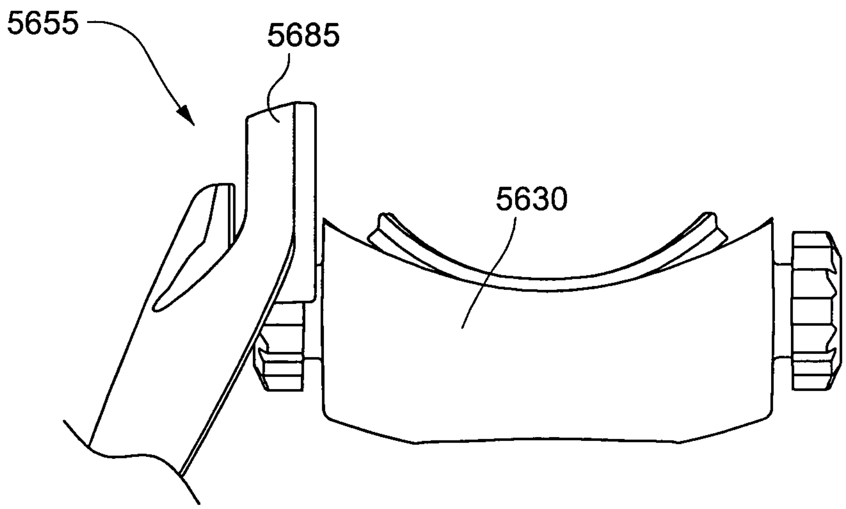

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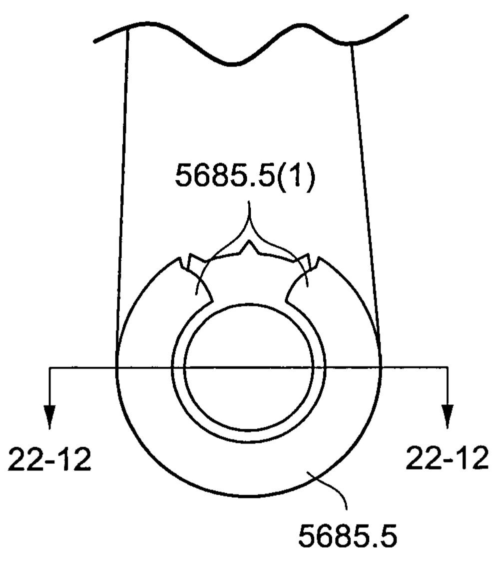

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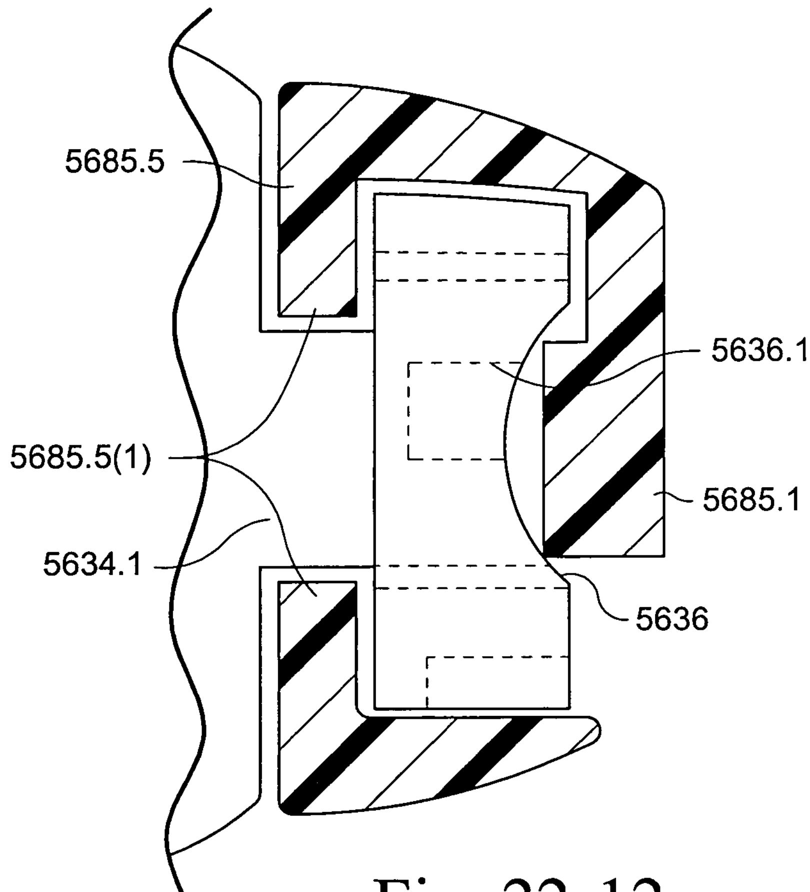

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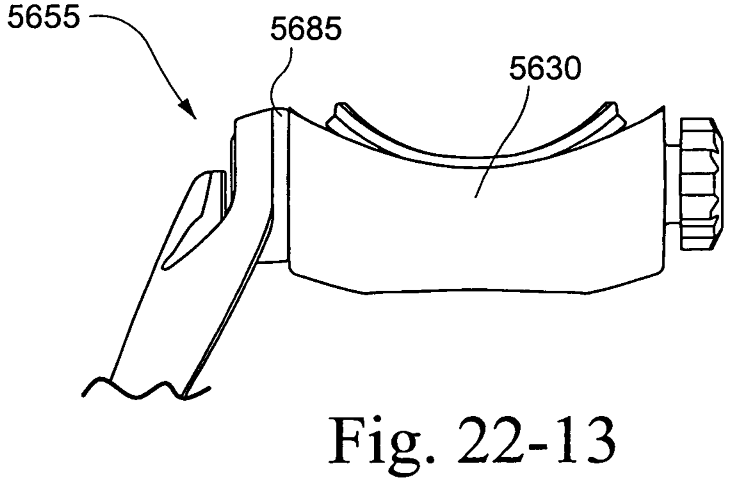

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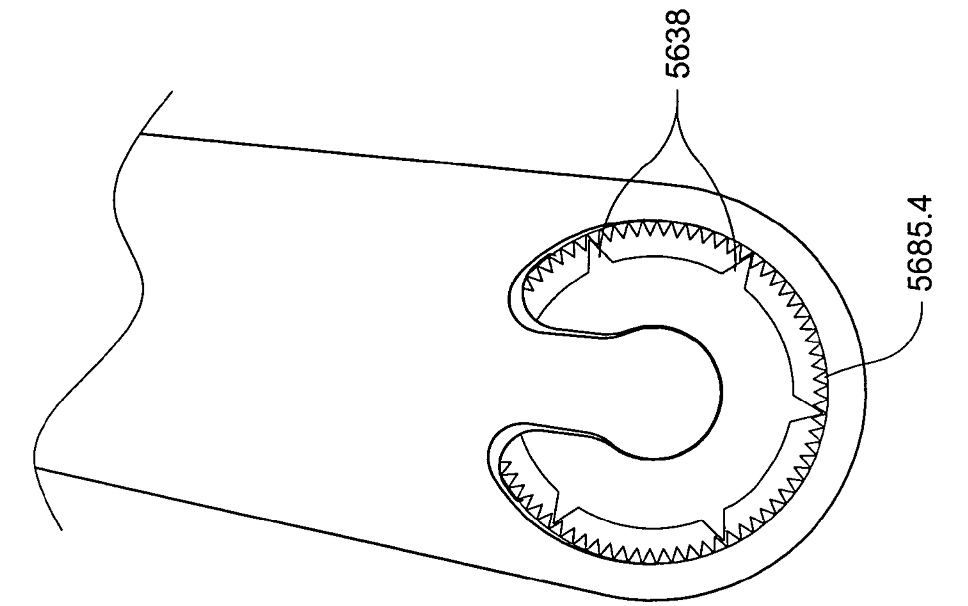

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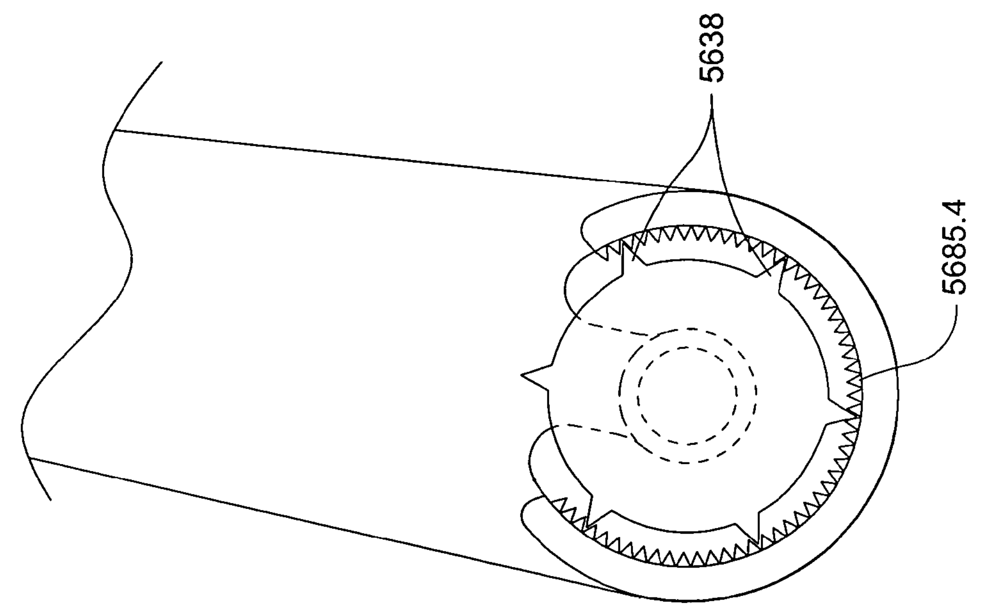

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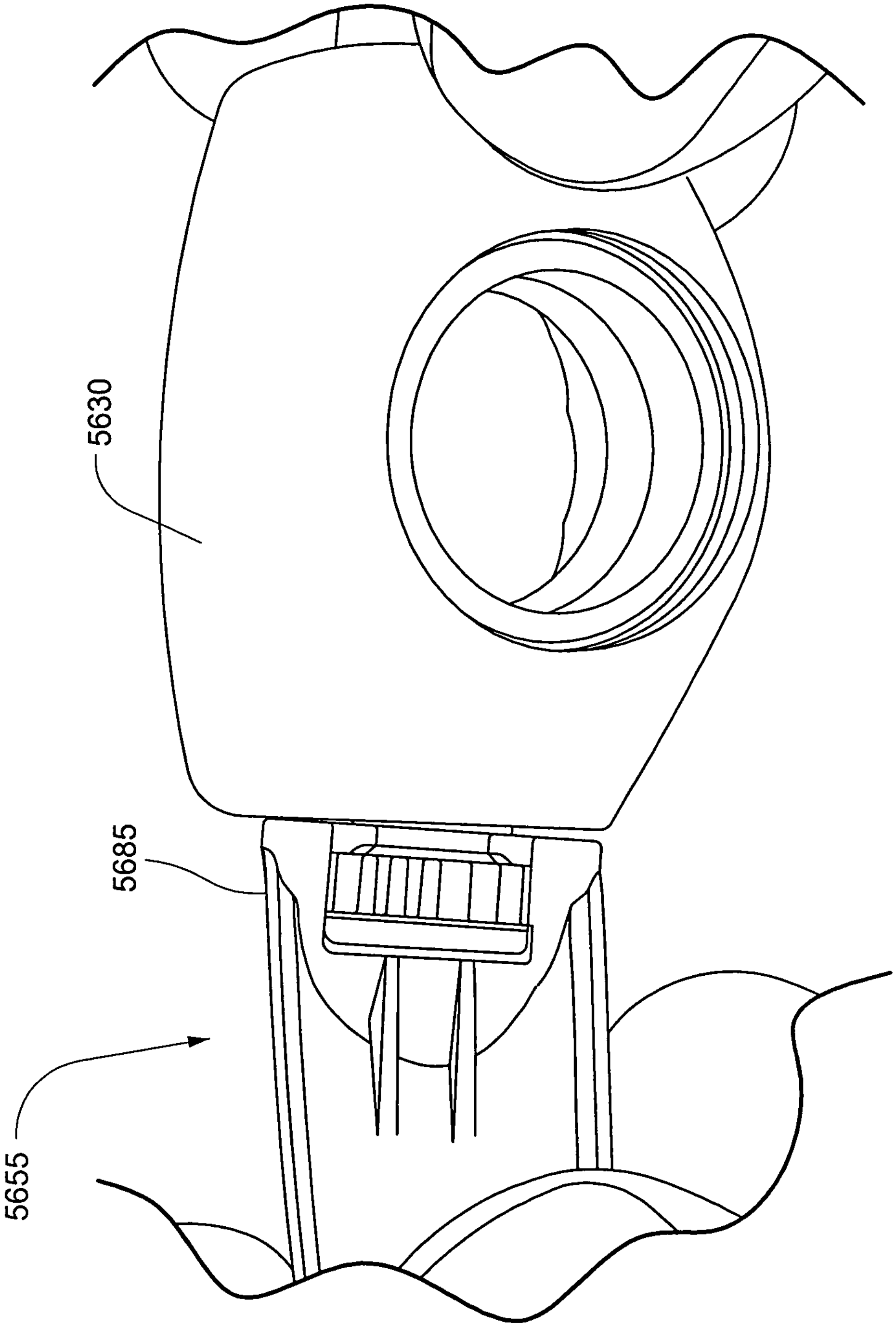

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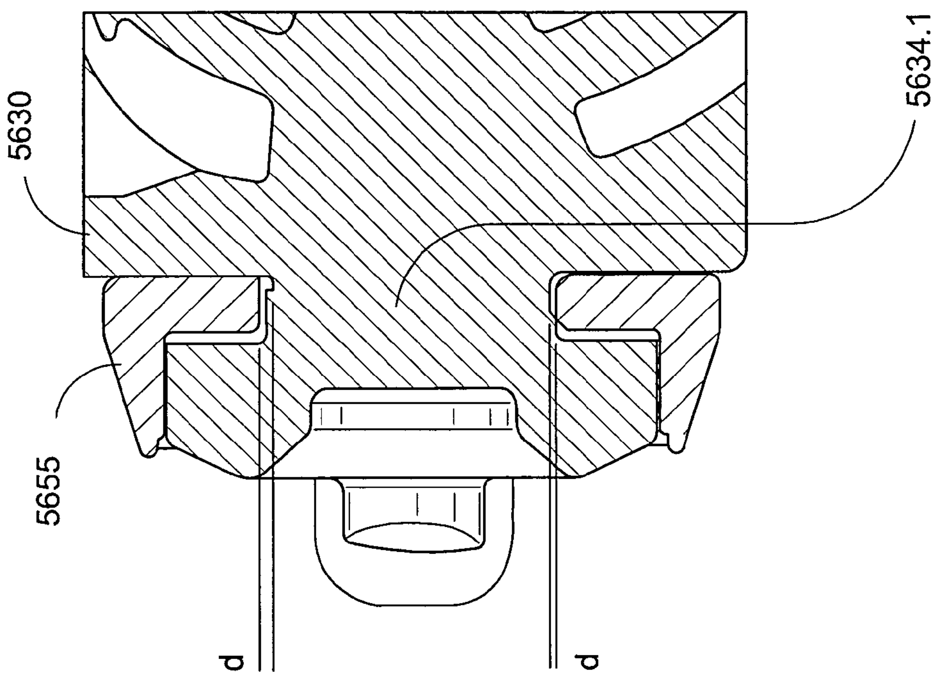
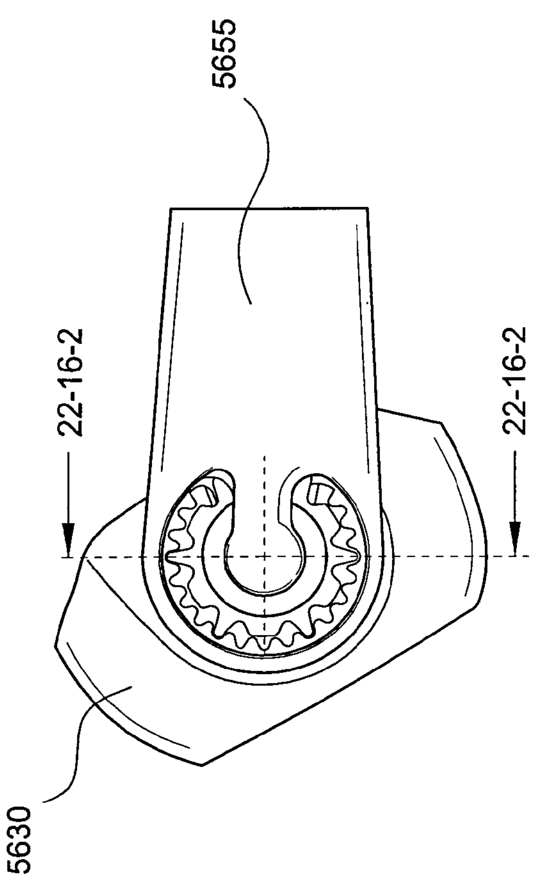


Fig. 22-16-2



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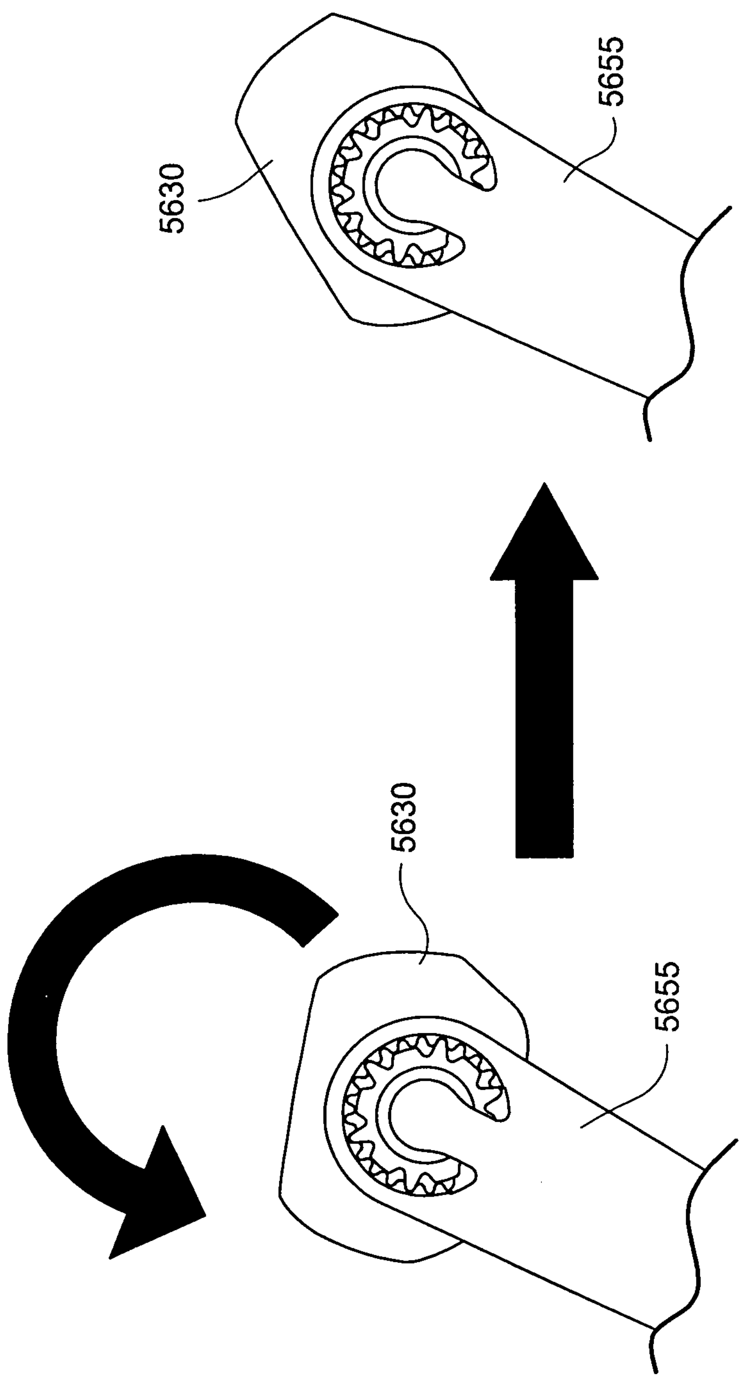
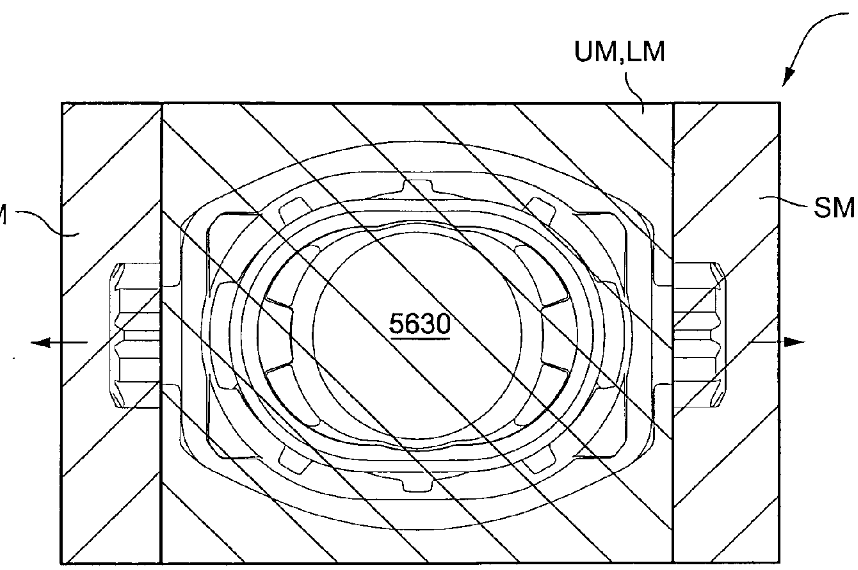


Fig. 22-17-2

Fig. 22-17-1



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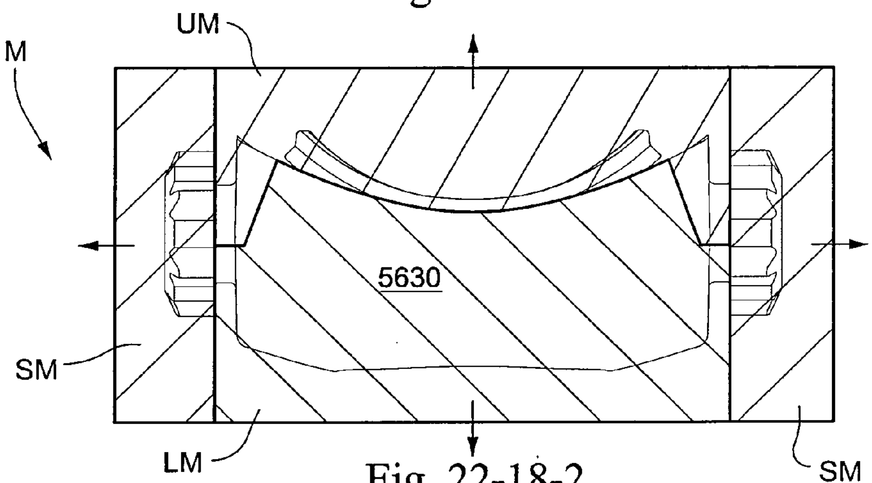

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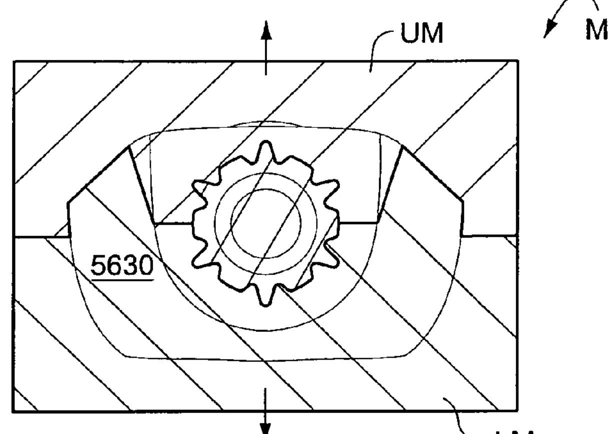

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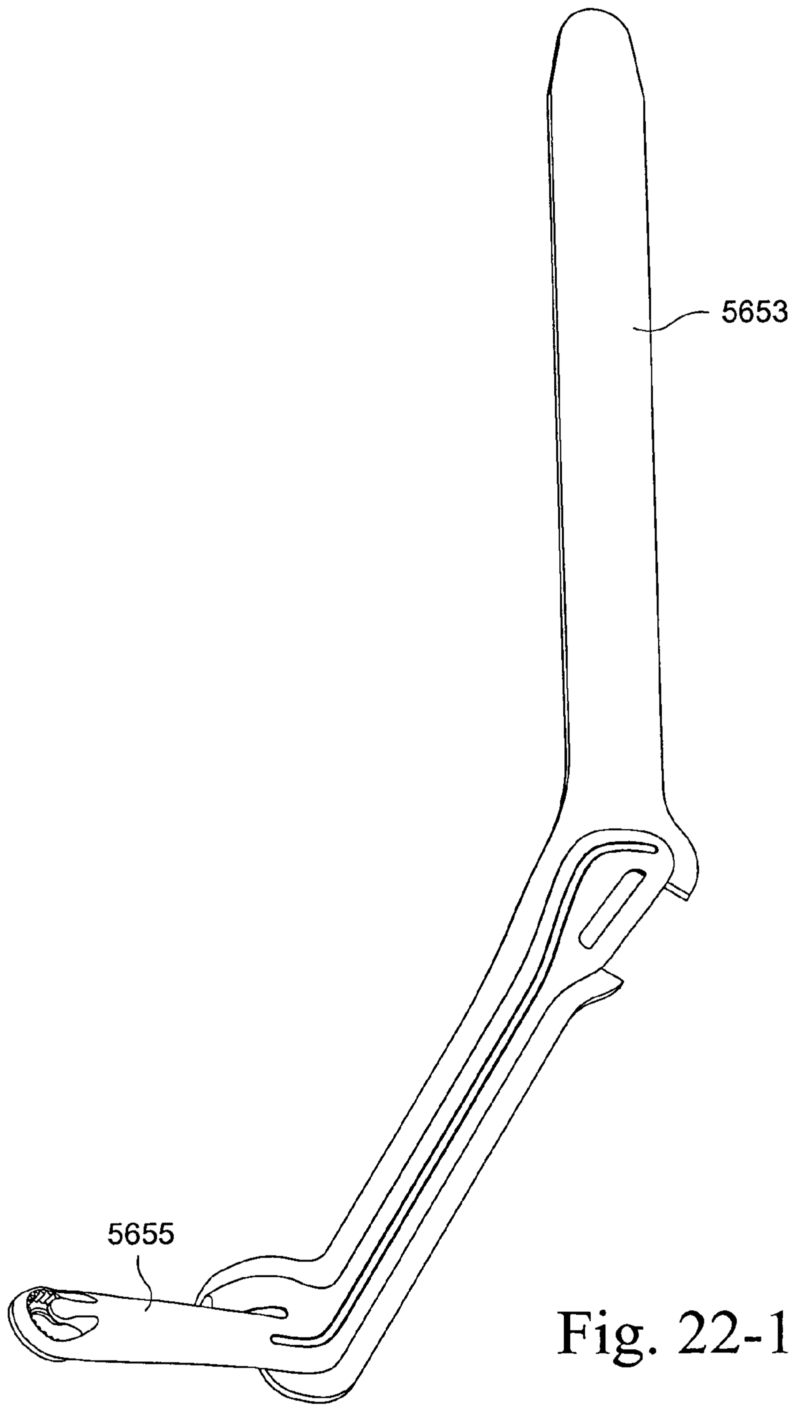

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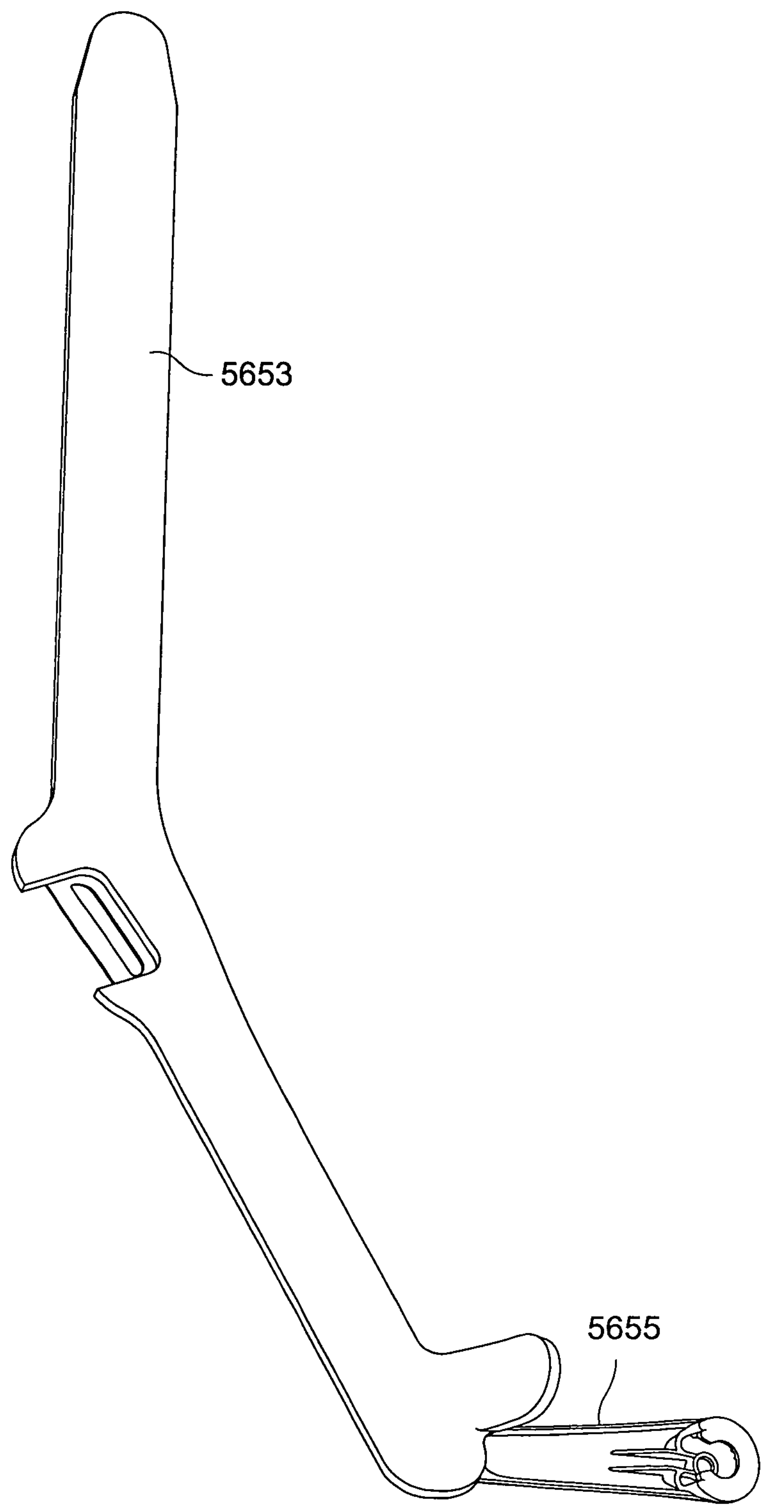

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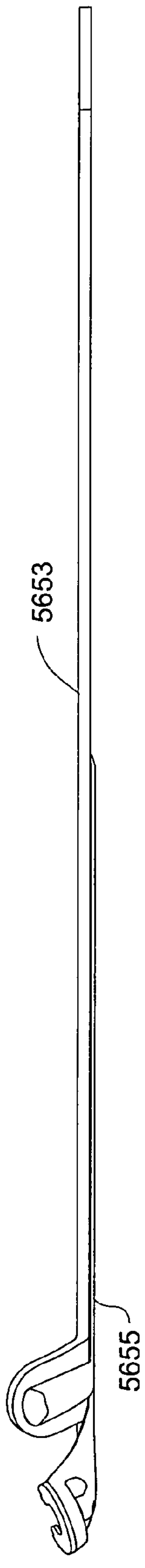

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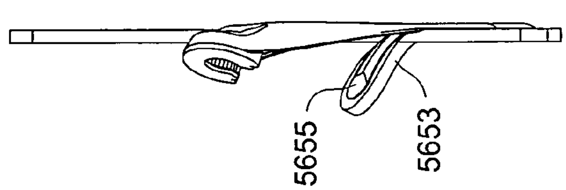
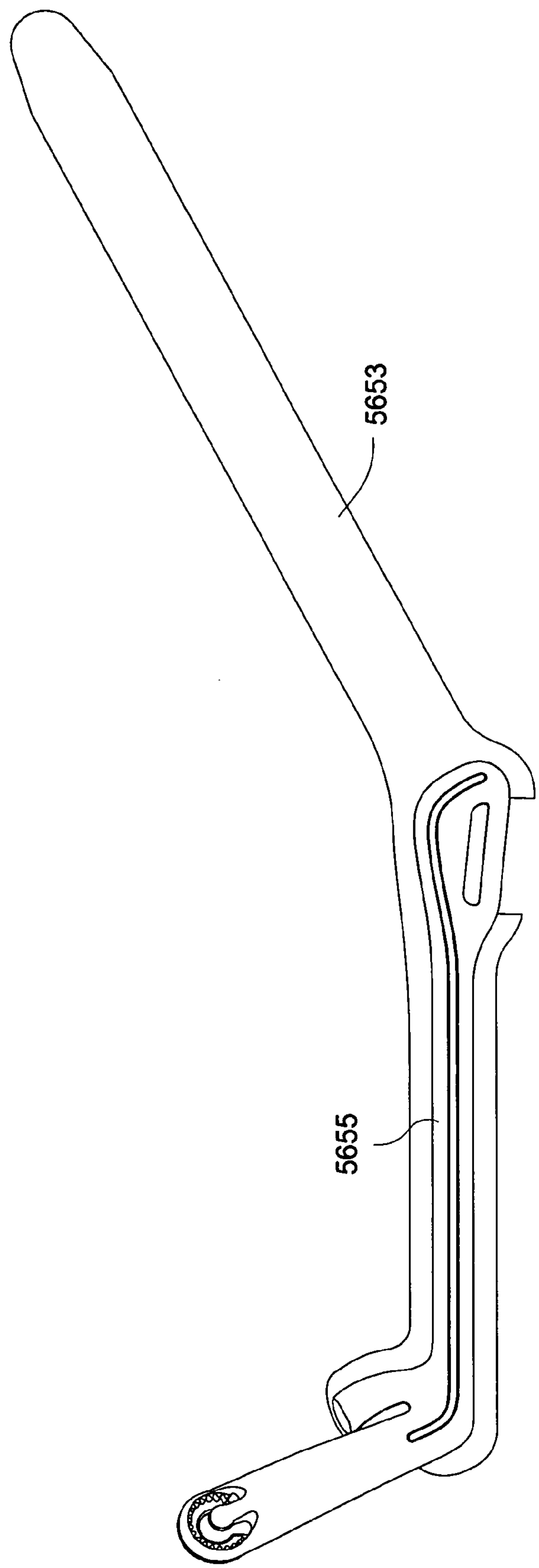


Fig. 22-19-4



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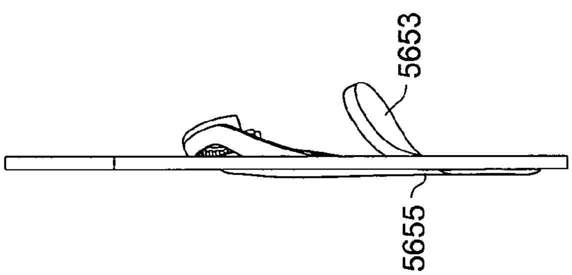

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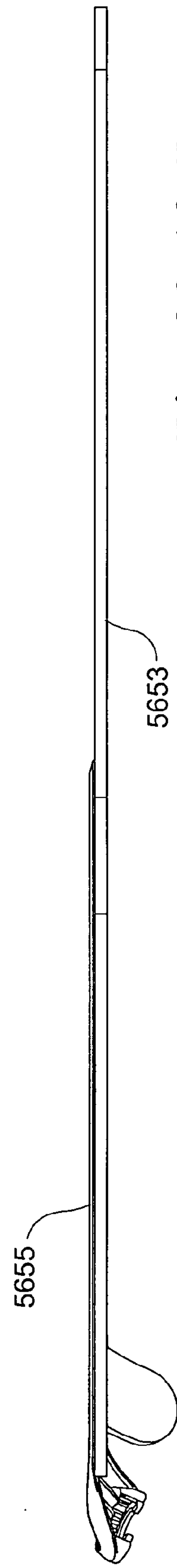

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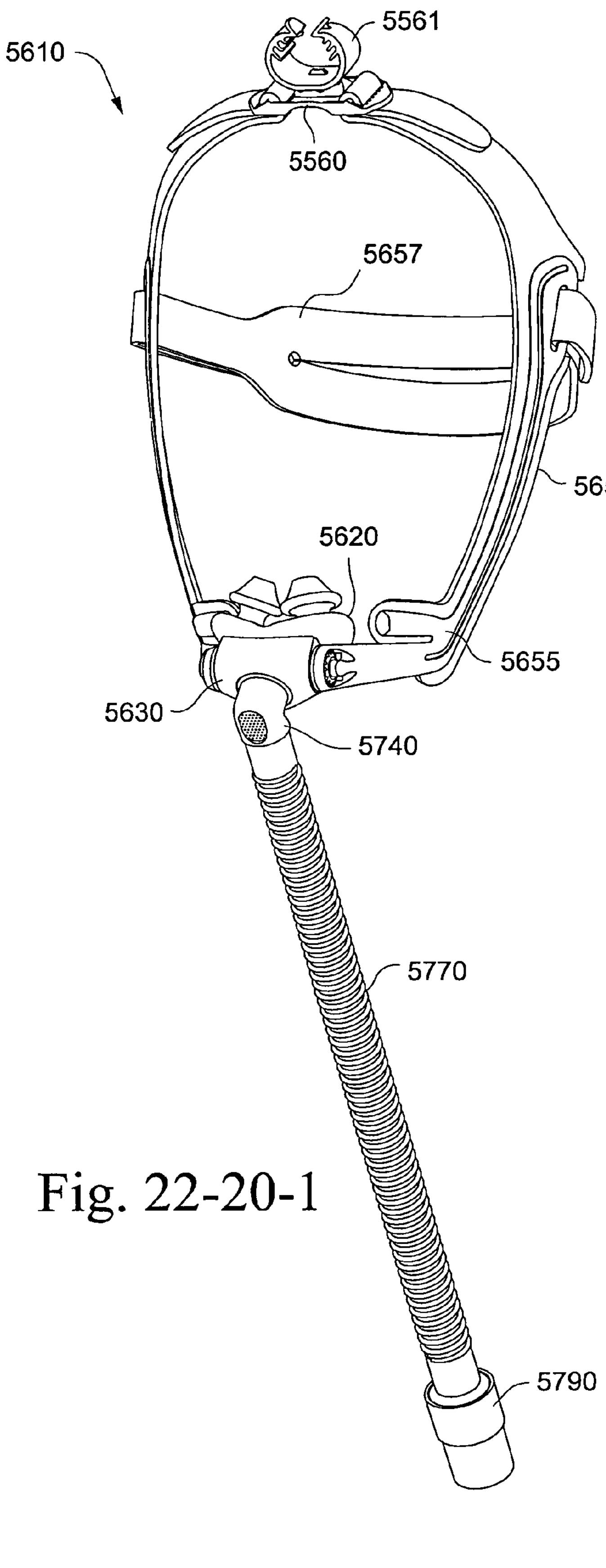

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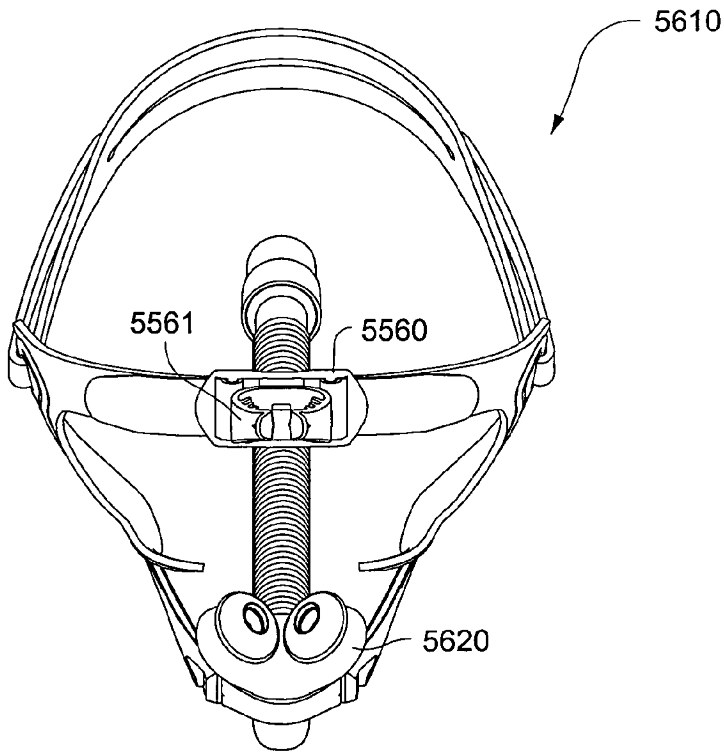

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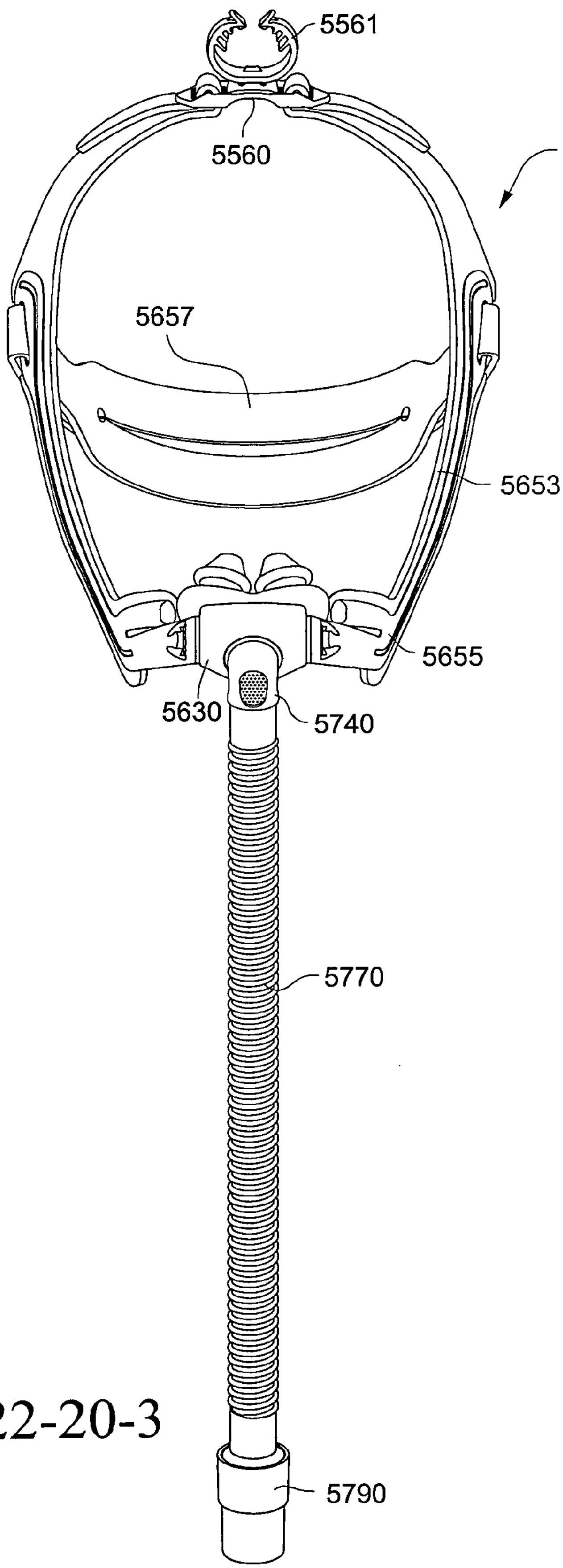

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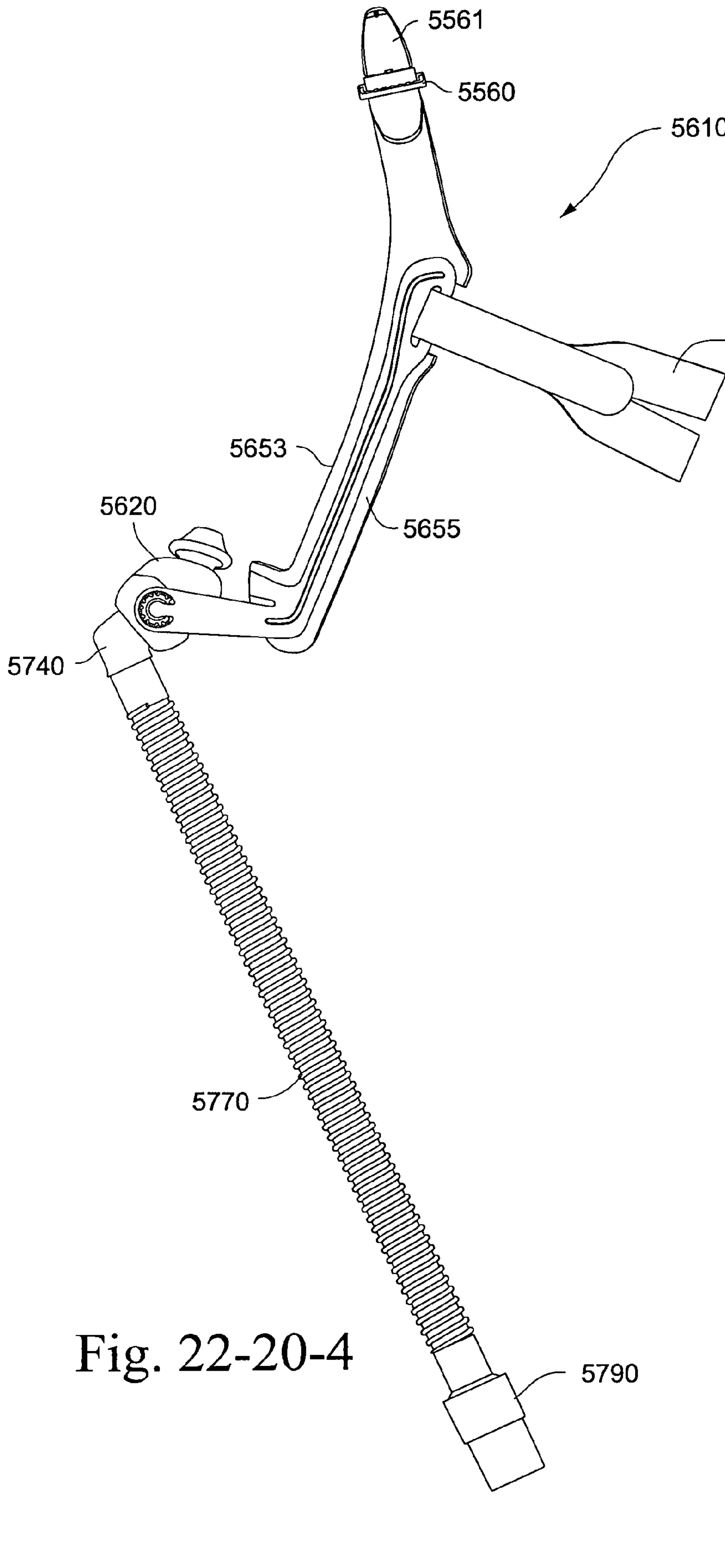

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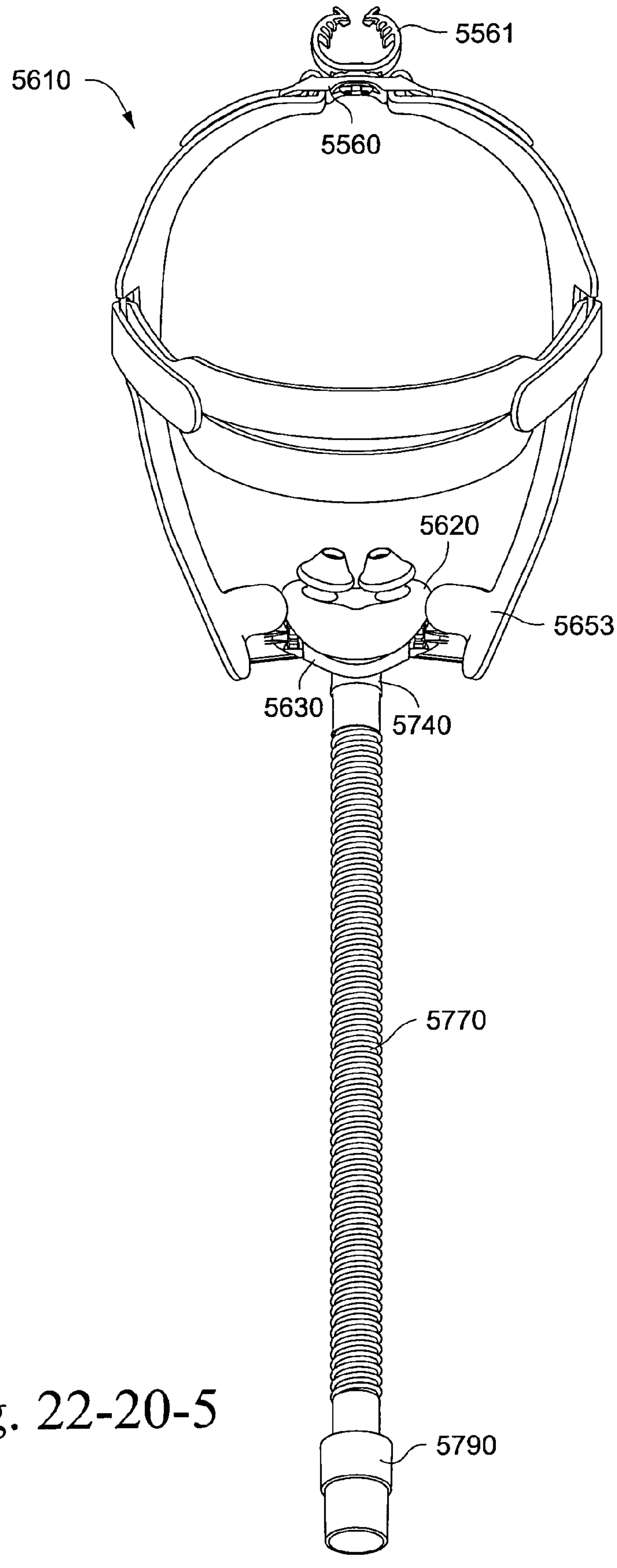

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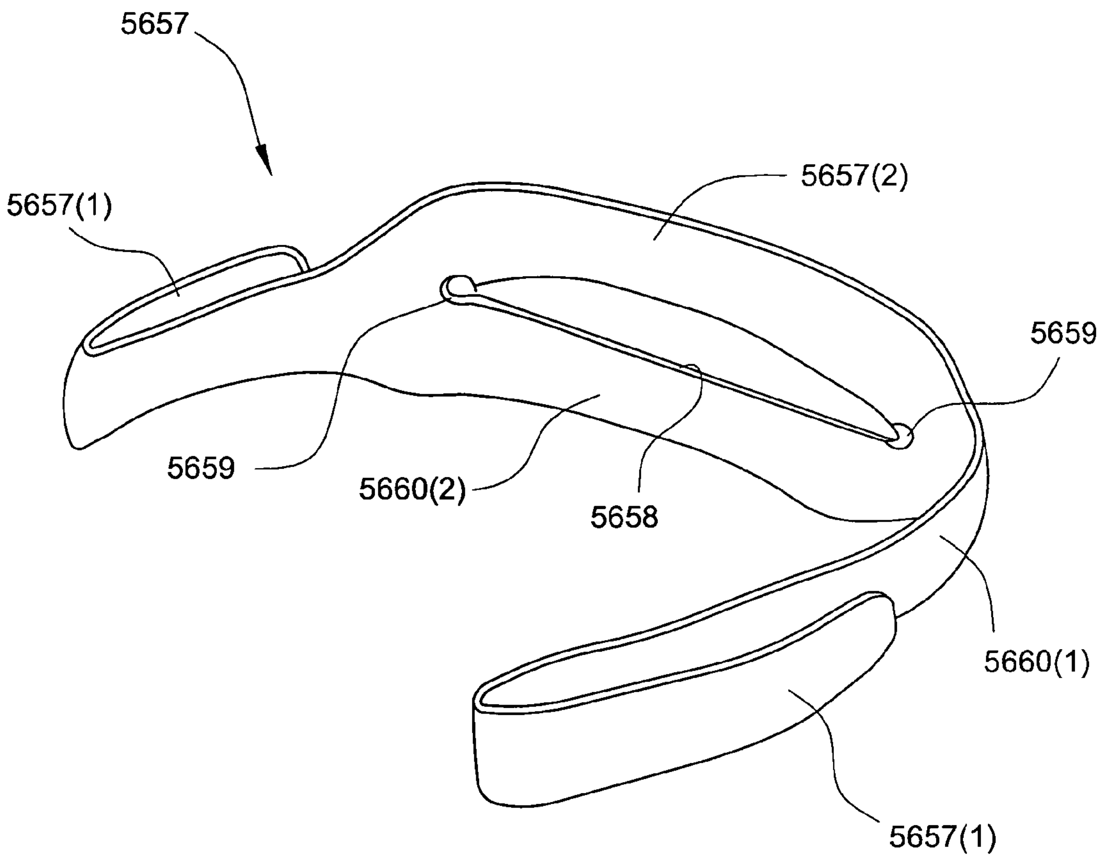

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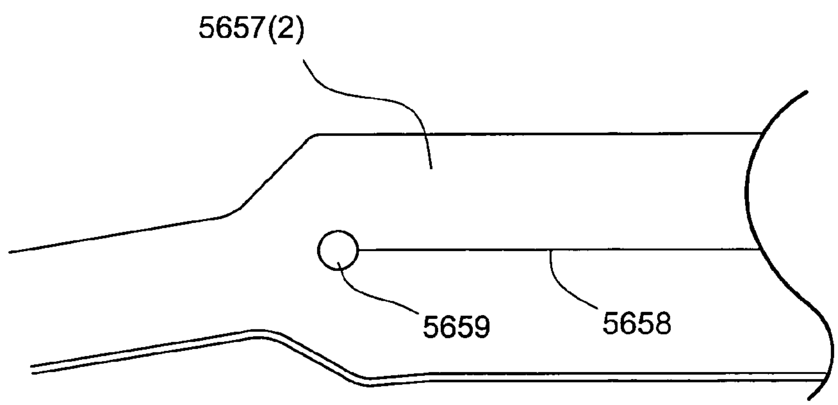

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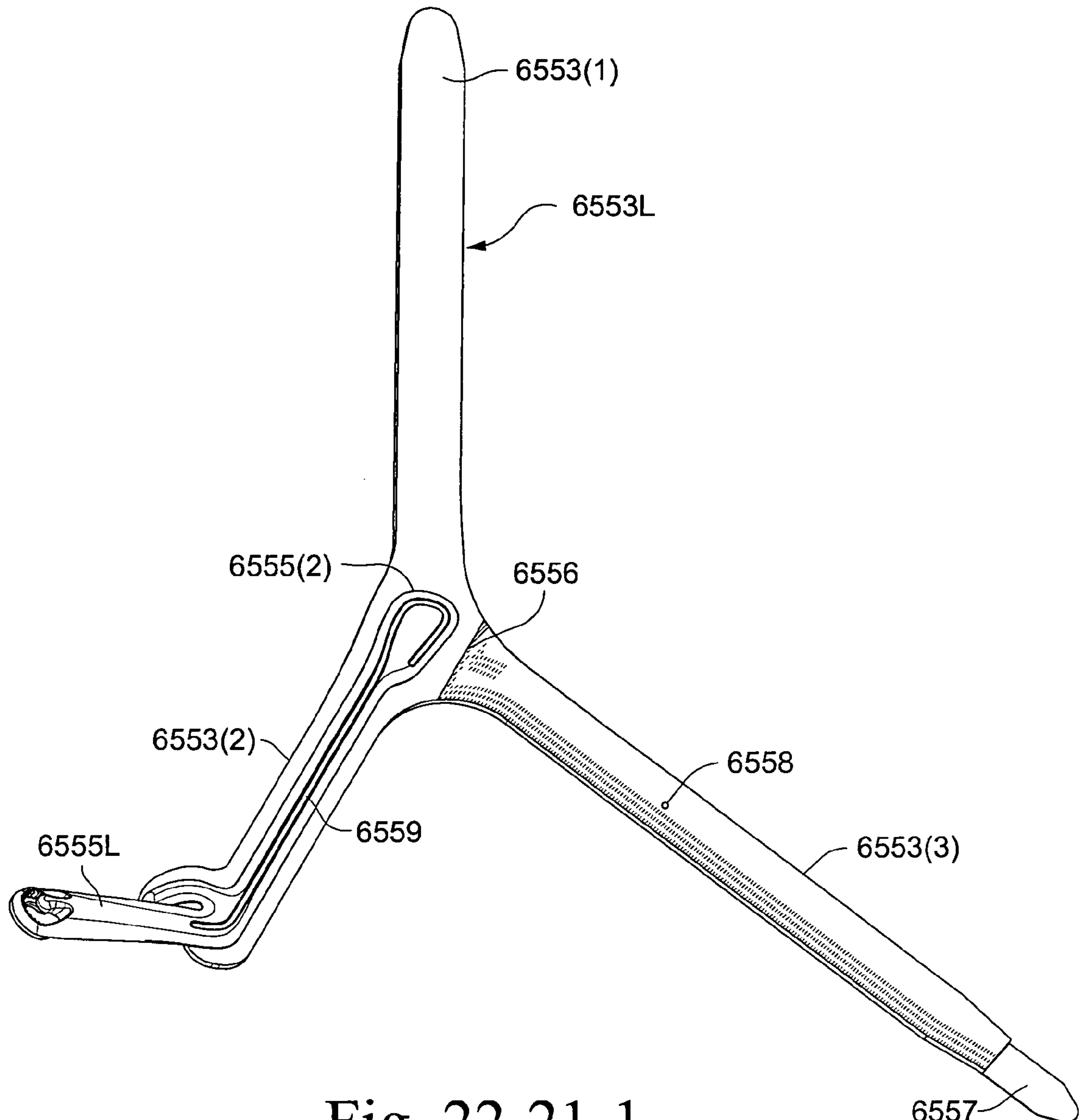

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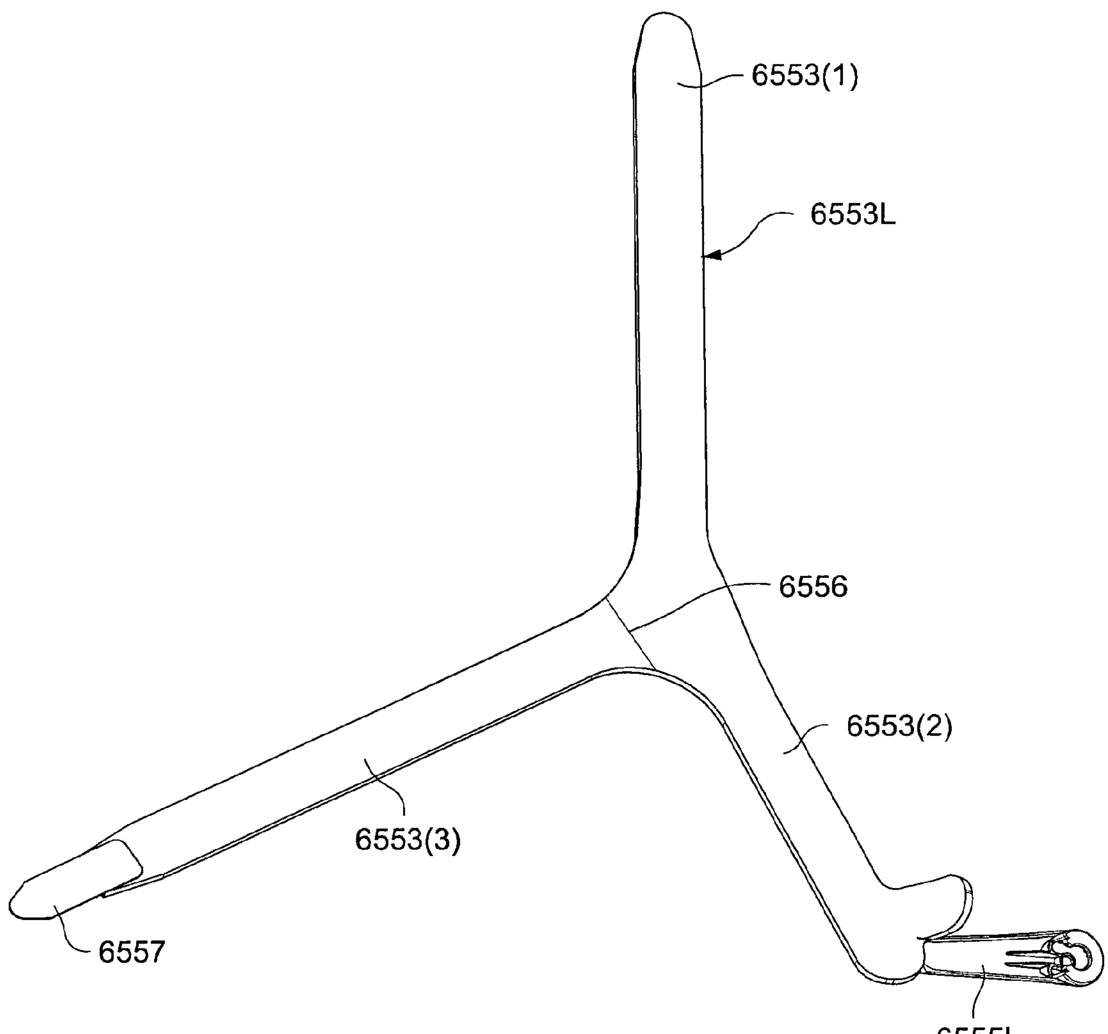

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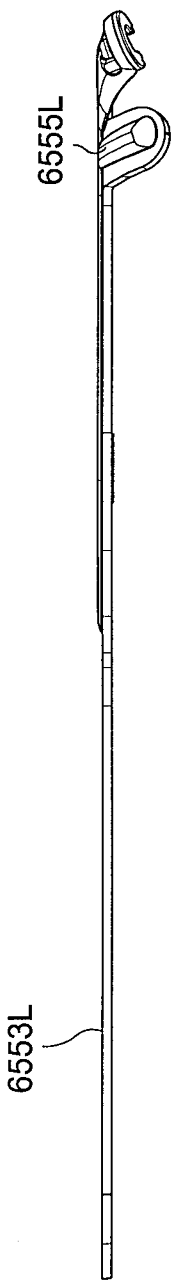

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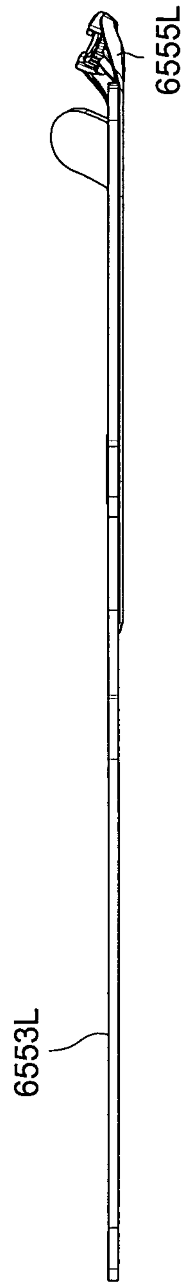

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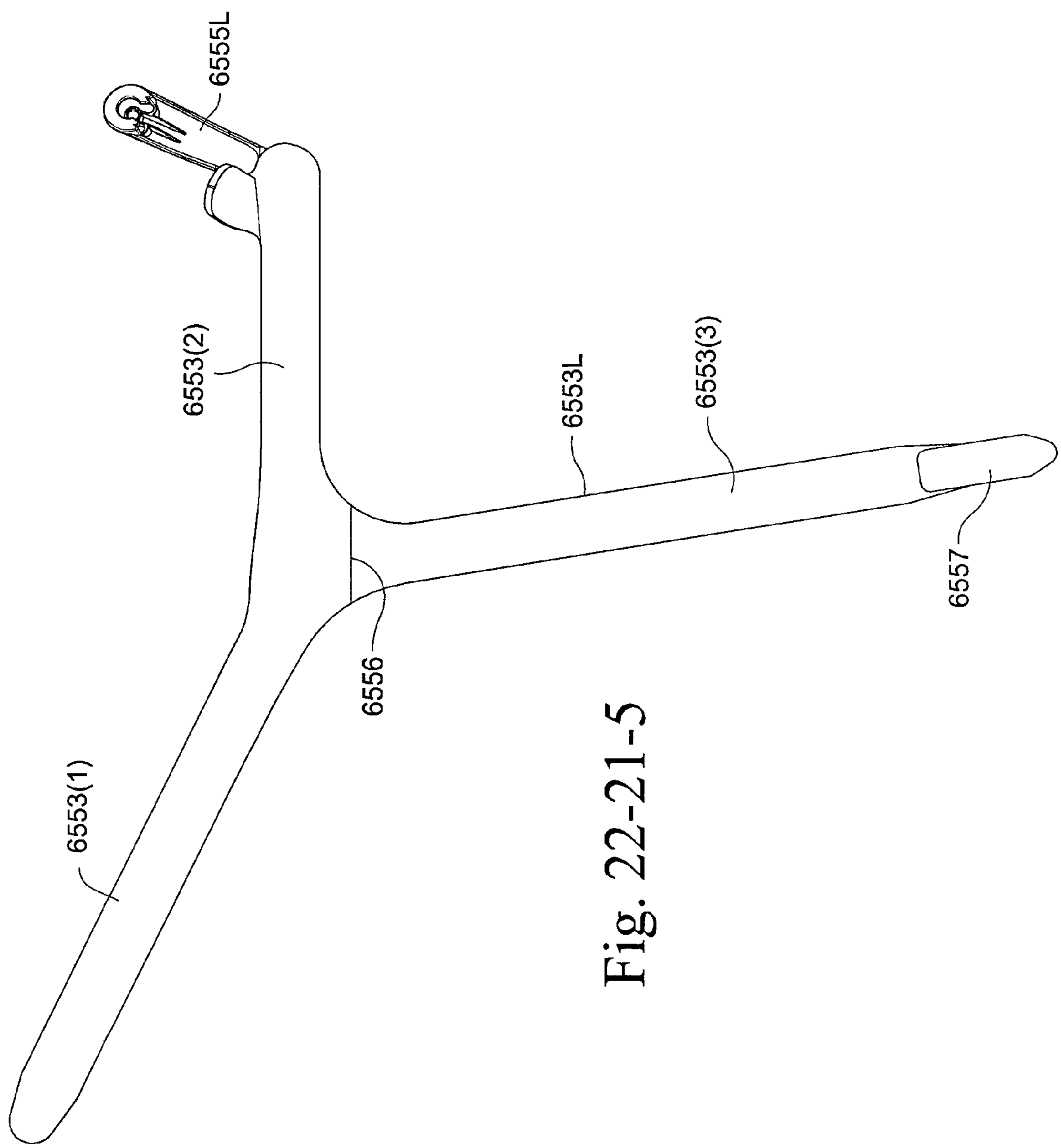

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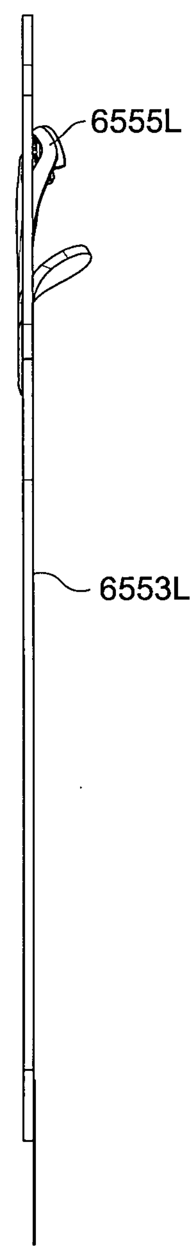


Fig. 22-21-6

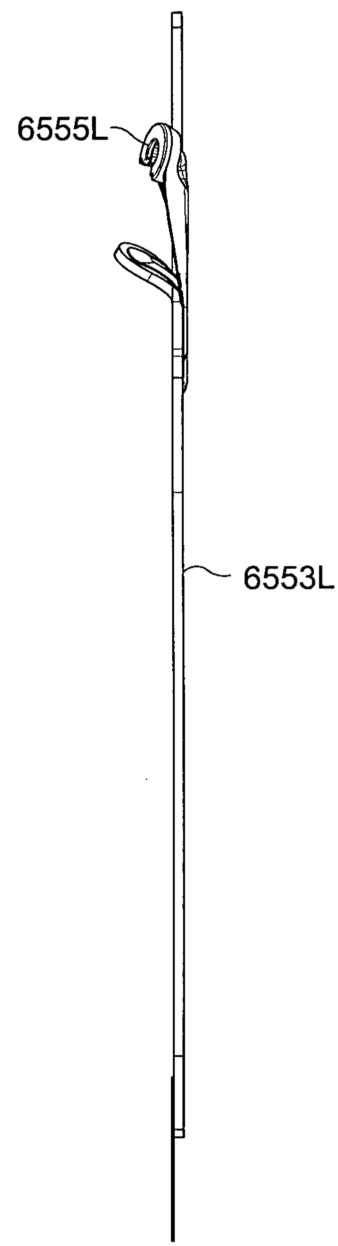


Fig. 22-21-7

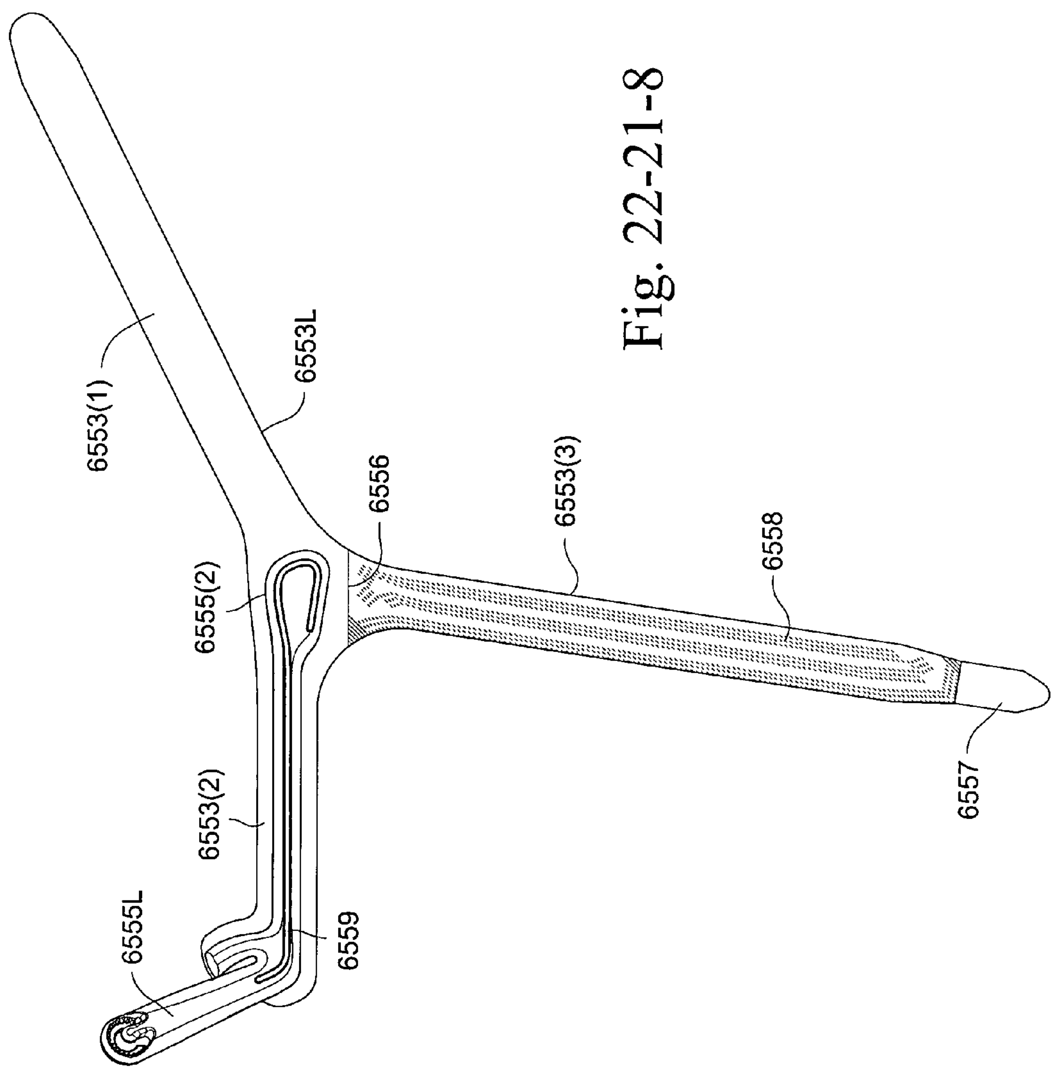


Fig. 22-21-8

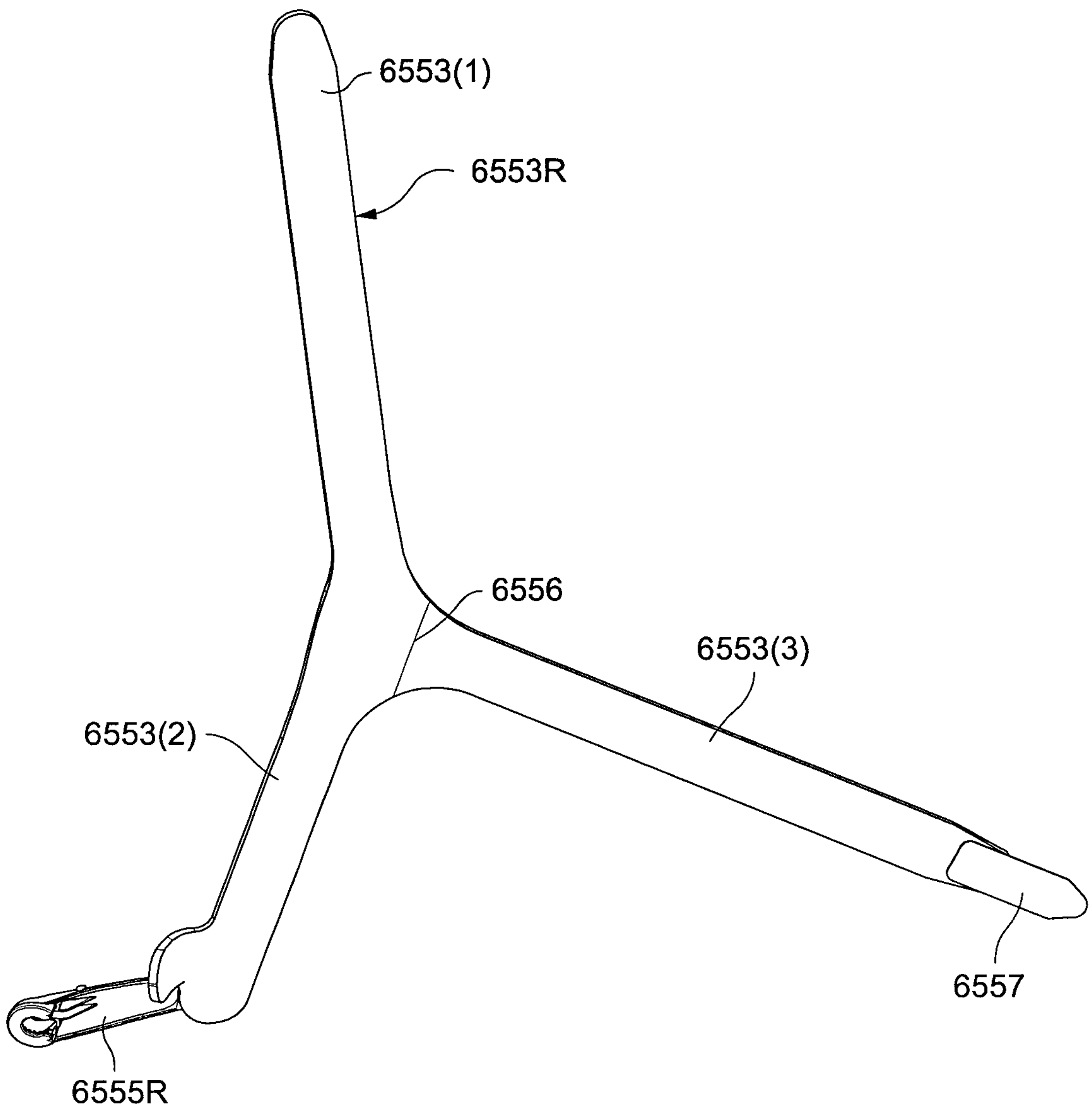


Fig. 22-22-1

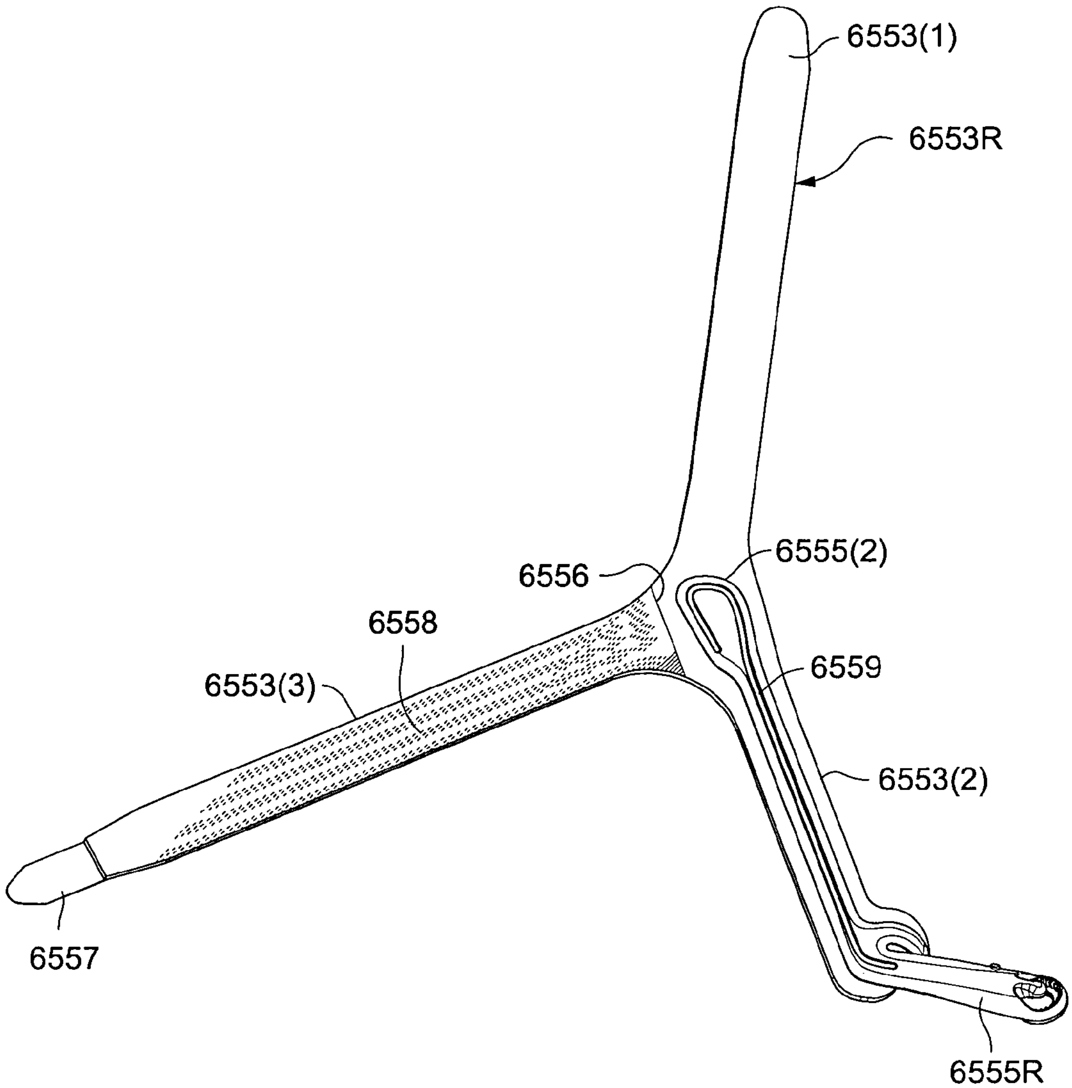


Fig. 22-22-2

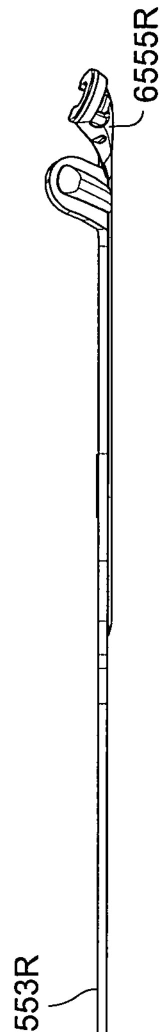


Fig. 22-22-3

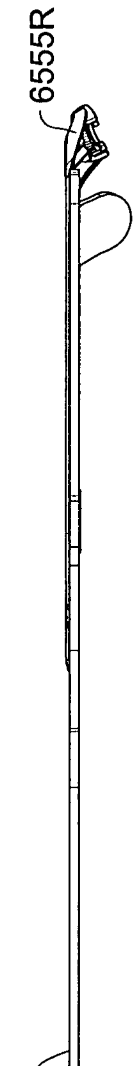


Fig. 22-22-4

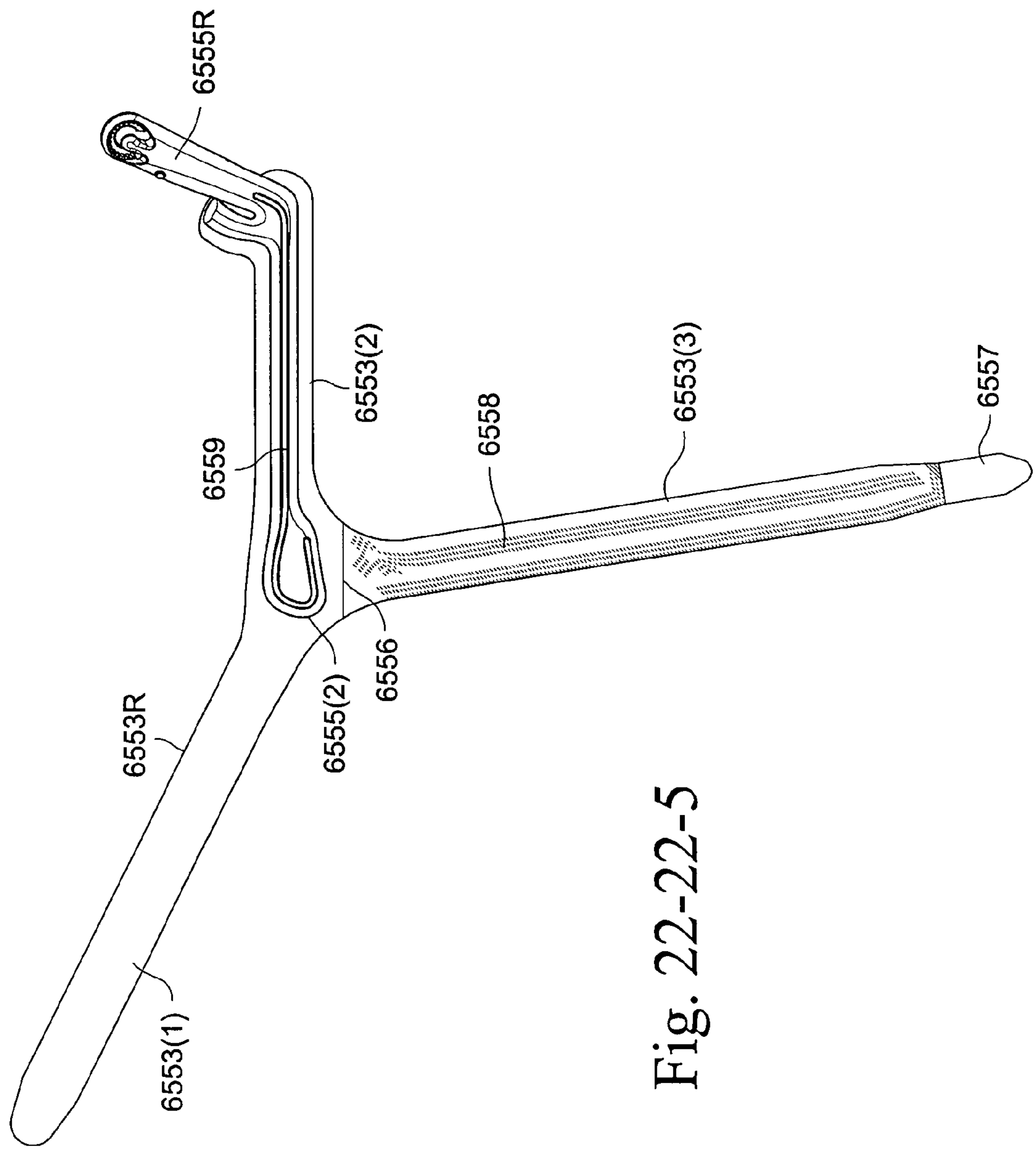


Fig. 22-22-5

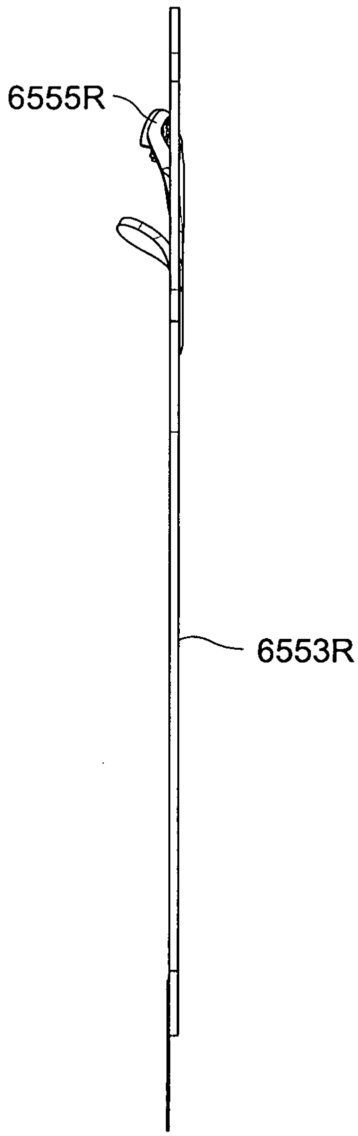


Fig. 22-22-6

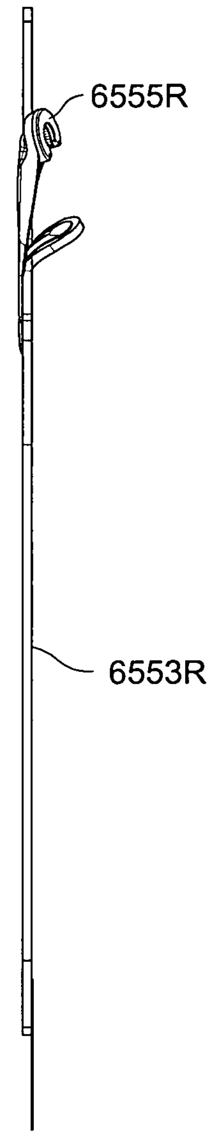


Fig. 22-22-7

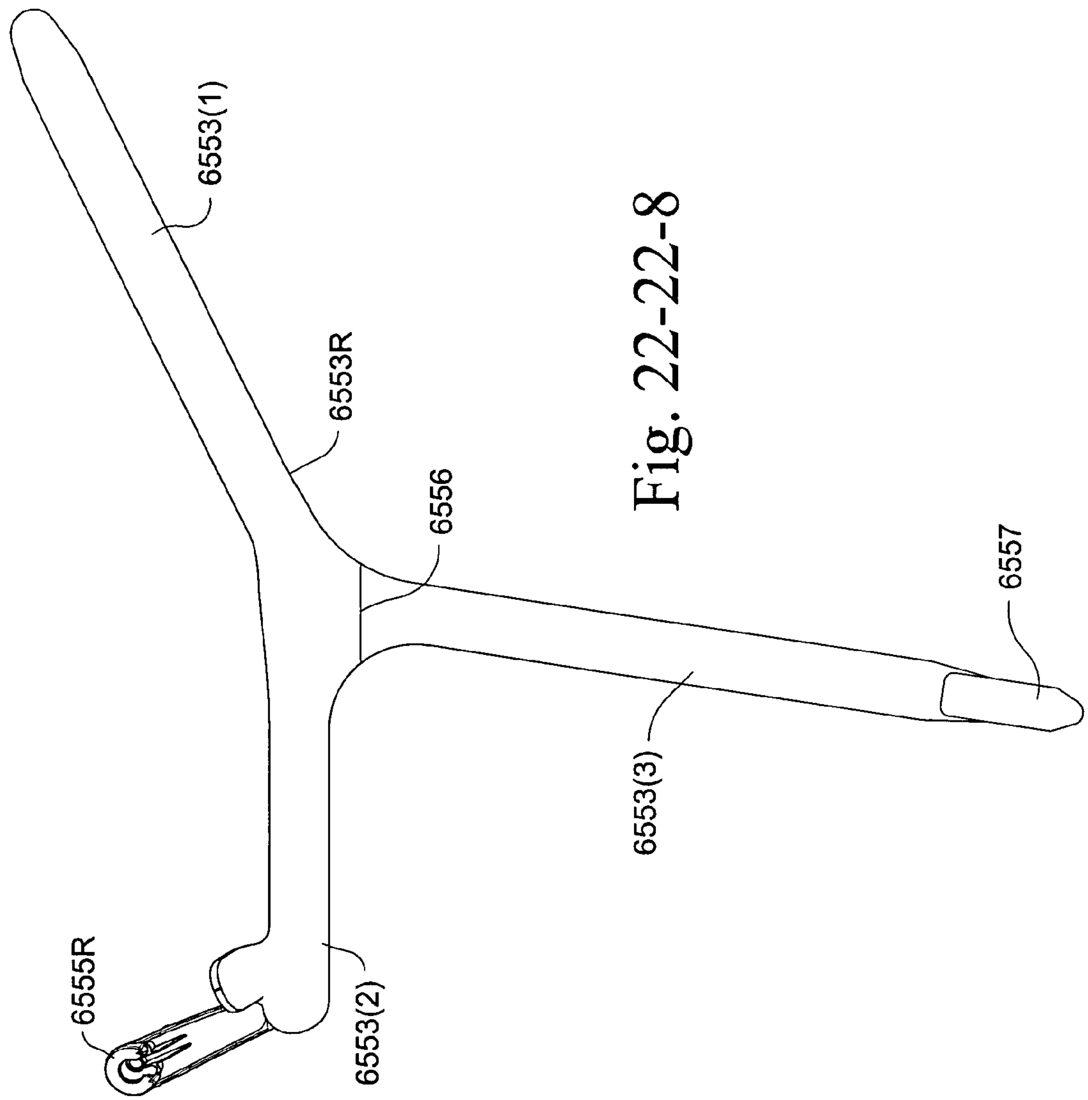


Fig. 22-22-8

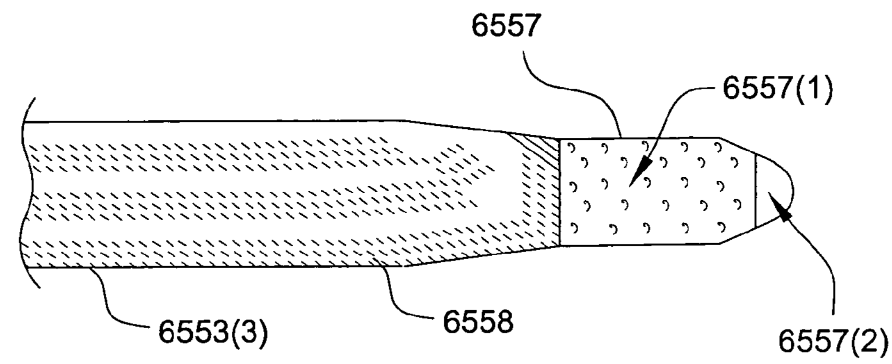


Fig. 22-22-9

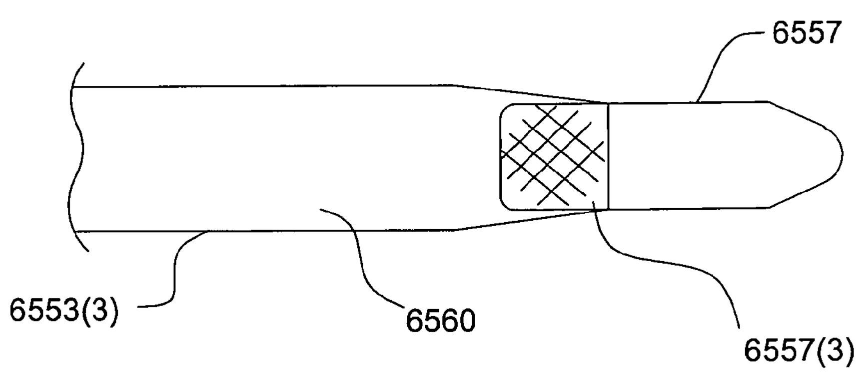


Fig. 22-22-10

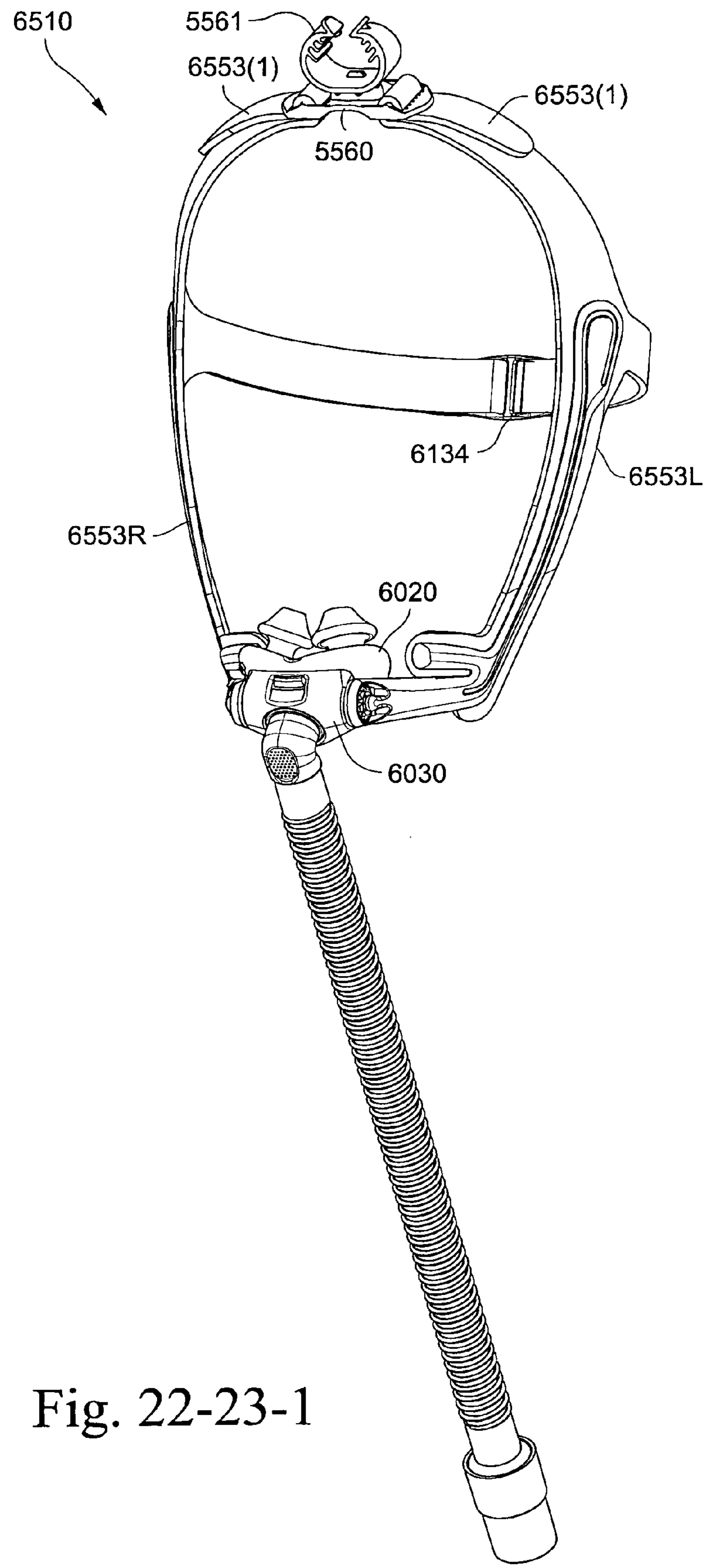


Fig. 22-23-1

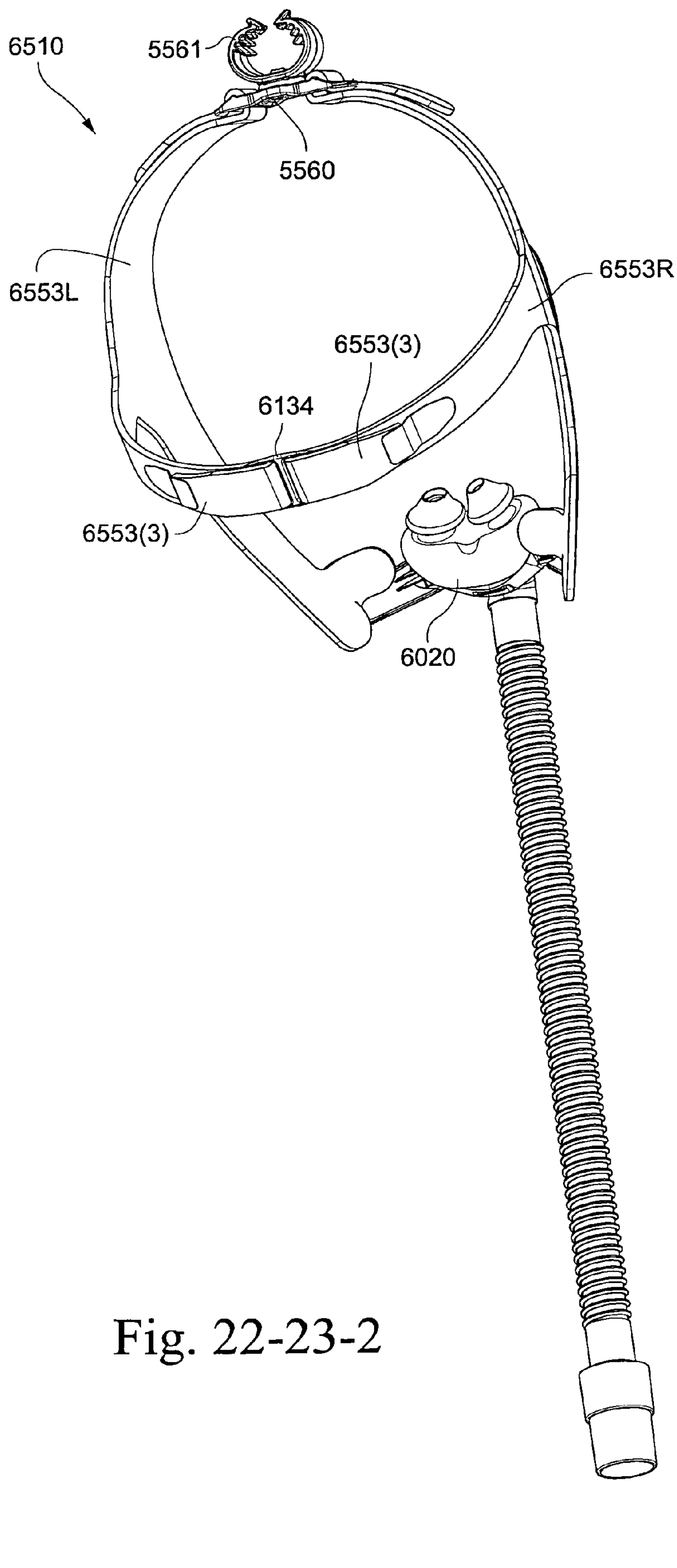


Fig. 22-23-2

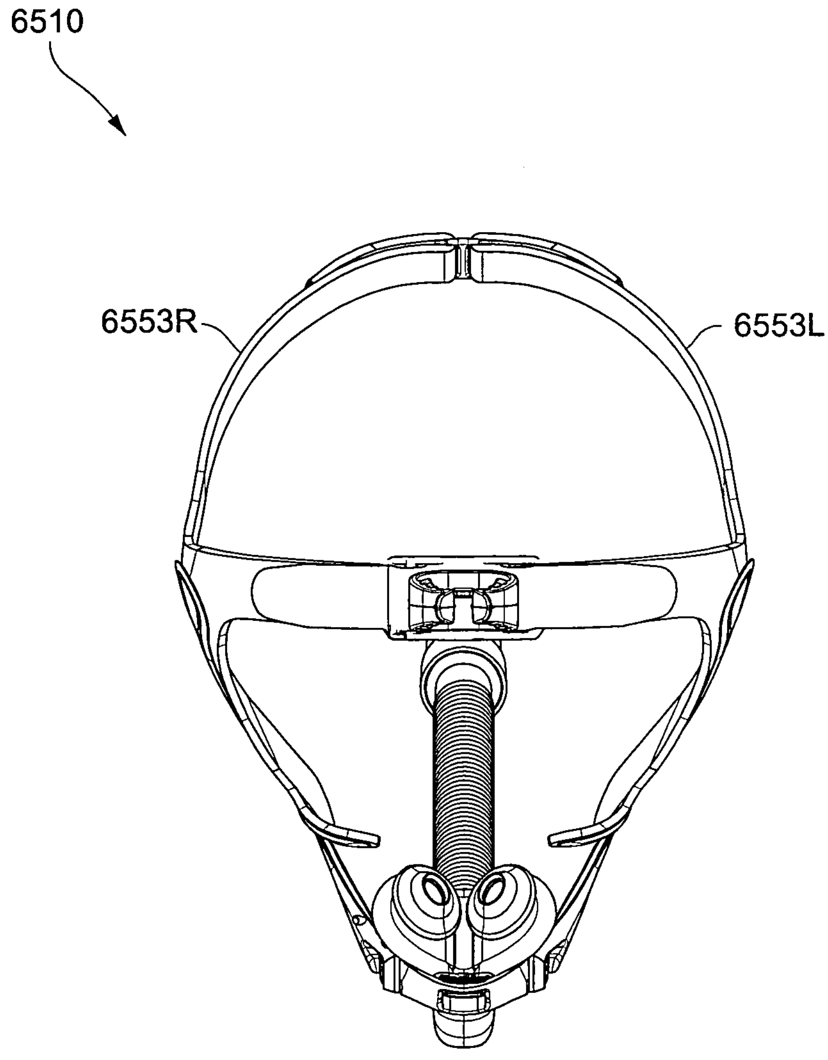


Fig. 22-23-3

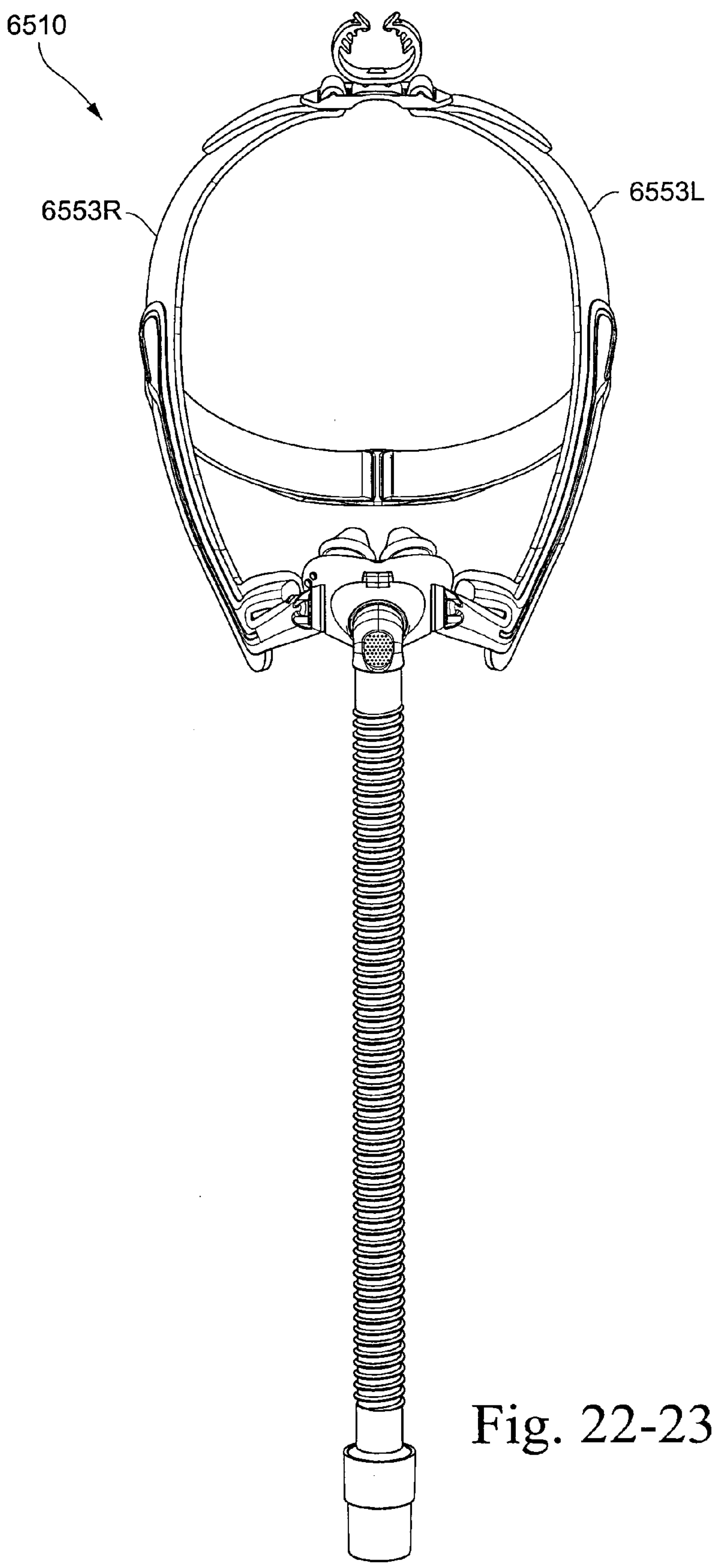


Fig. 22-23-4

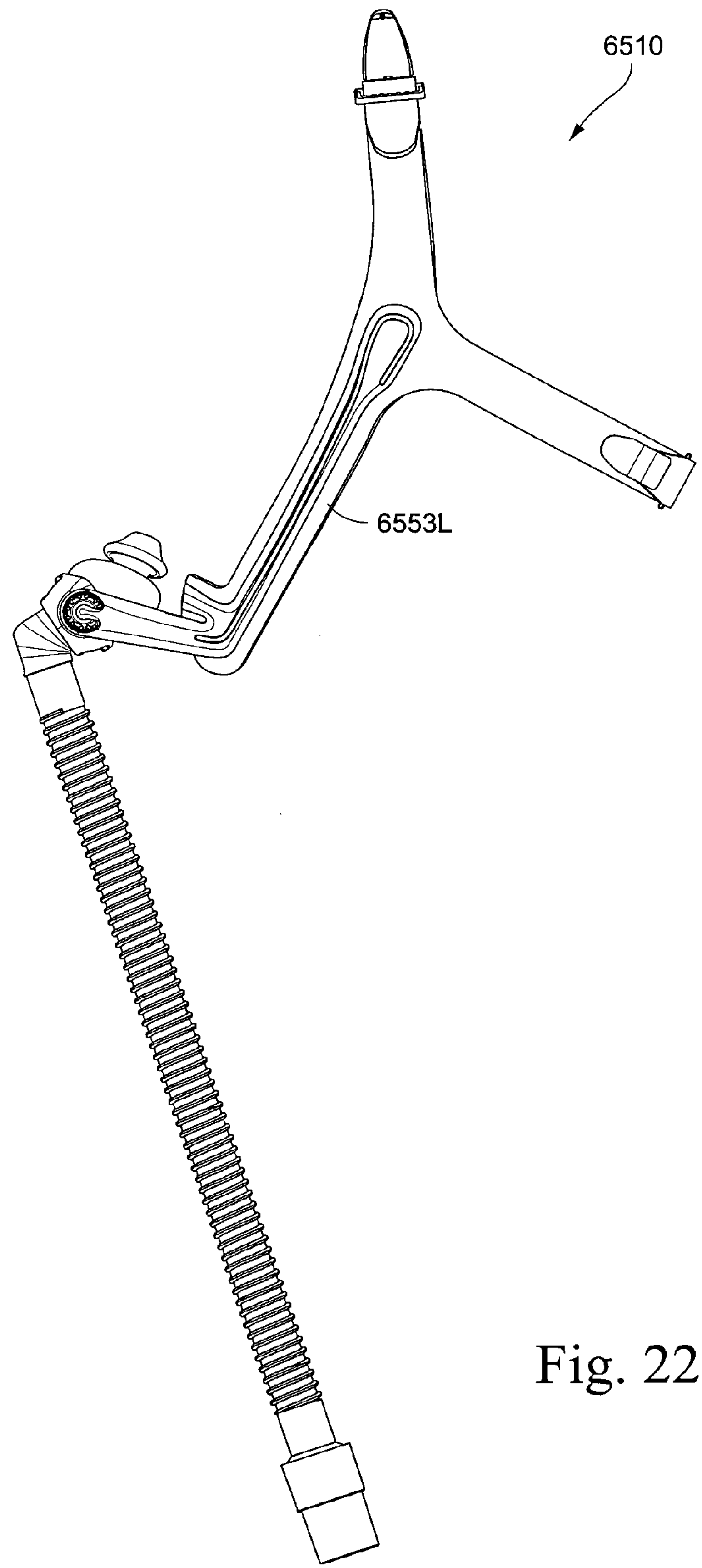


Fig. 22-23-5

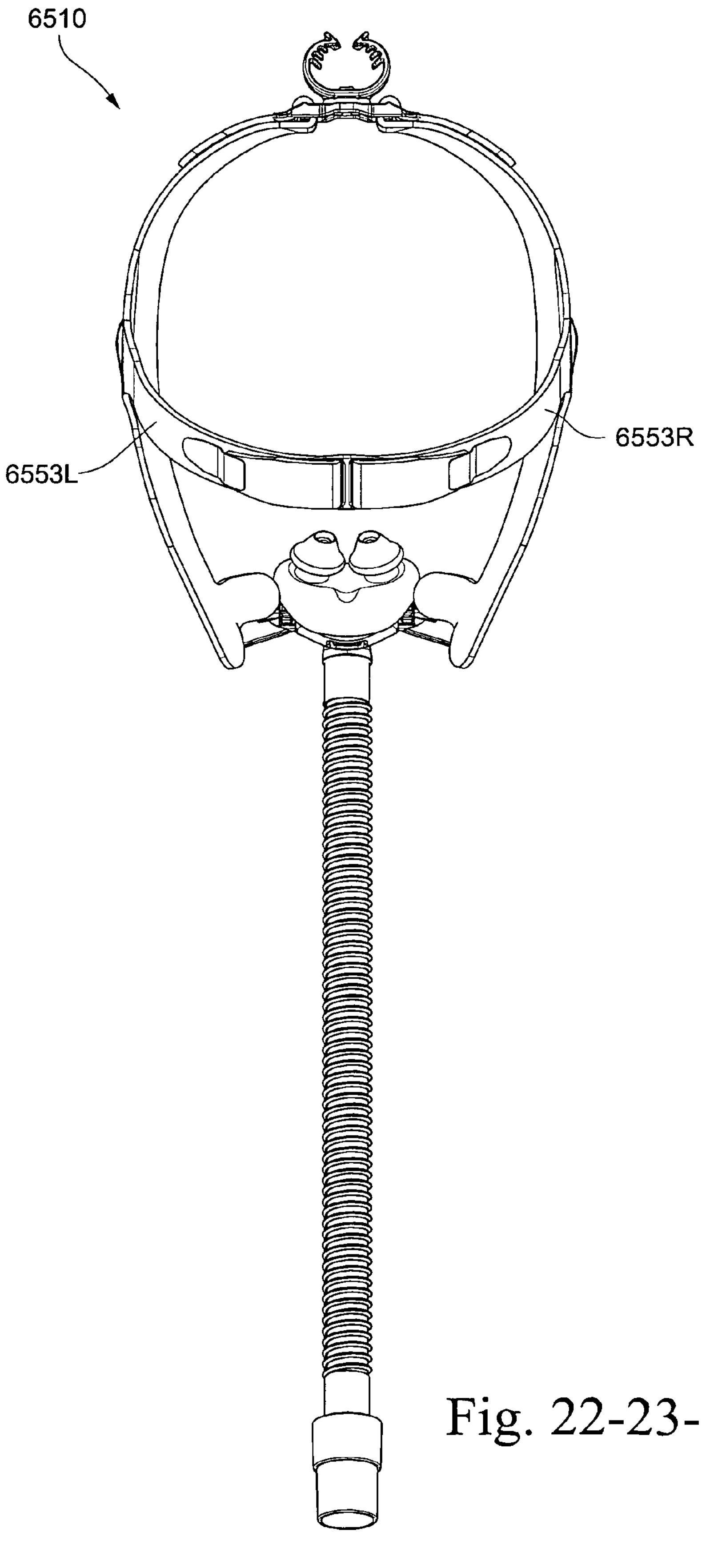


Fig. 22-23-6

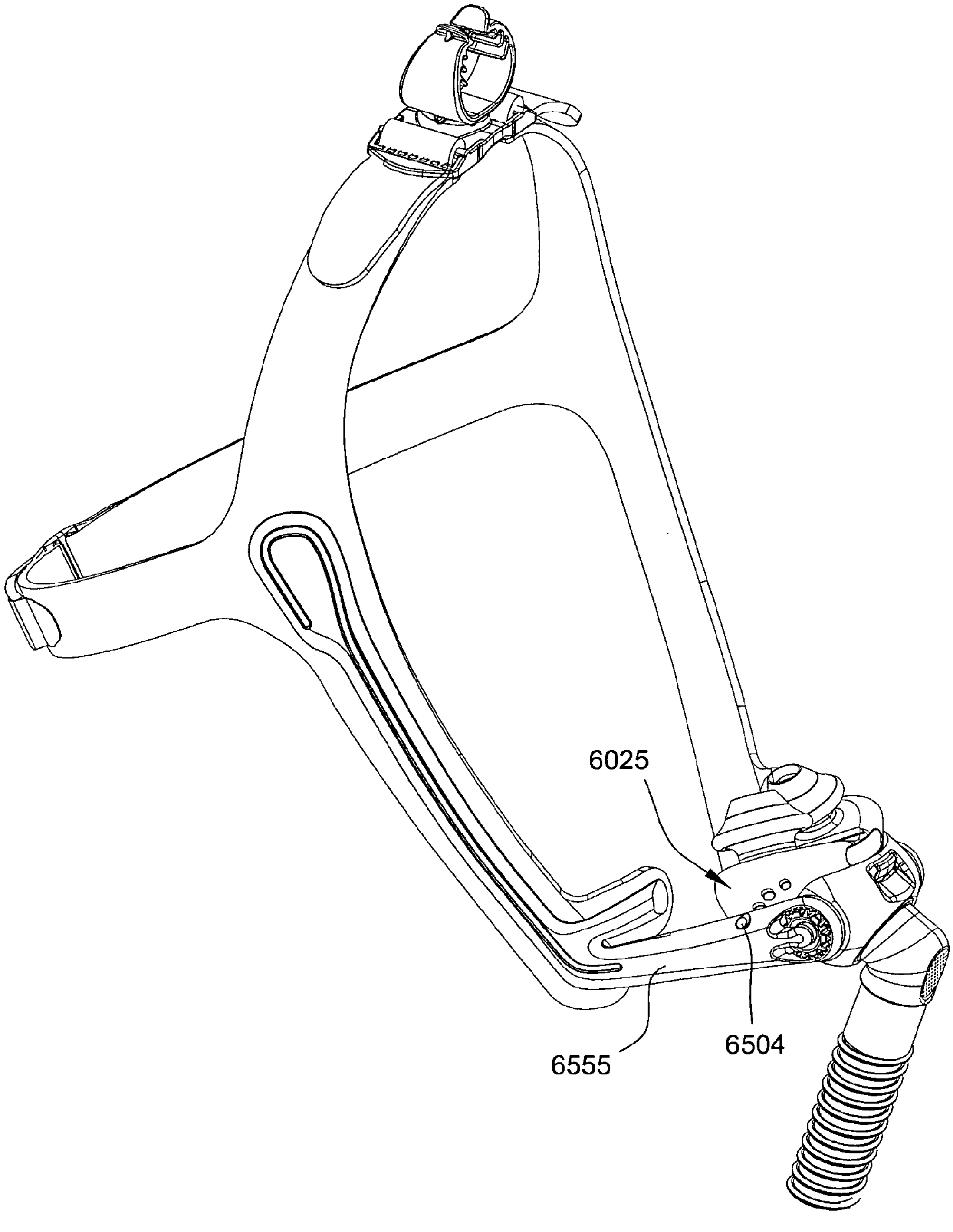


Fig. 22-23-7

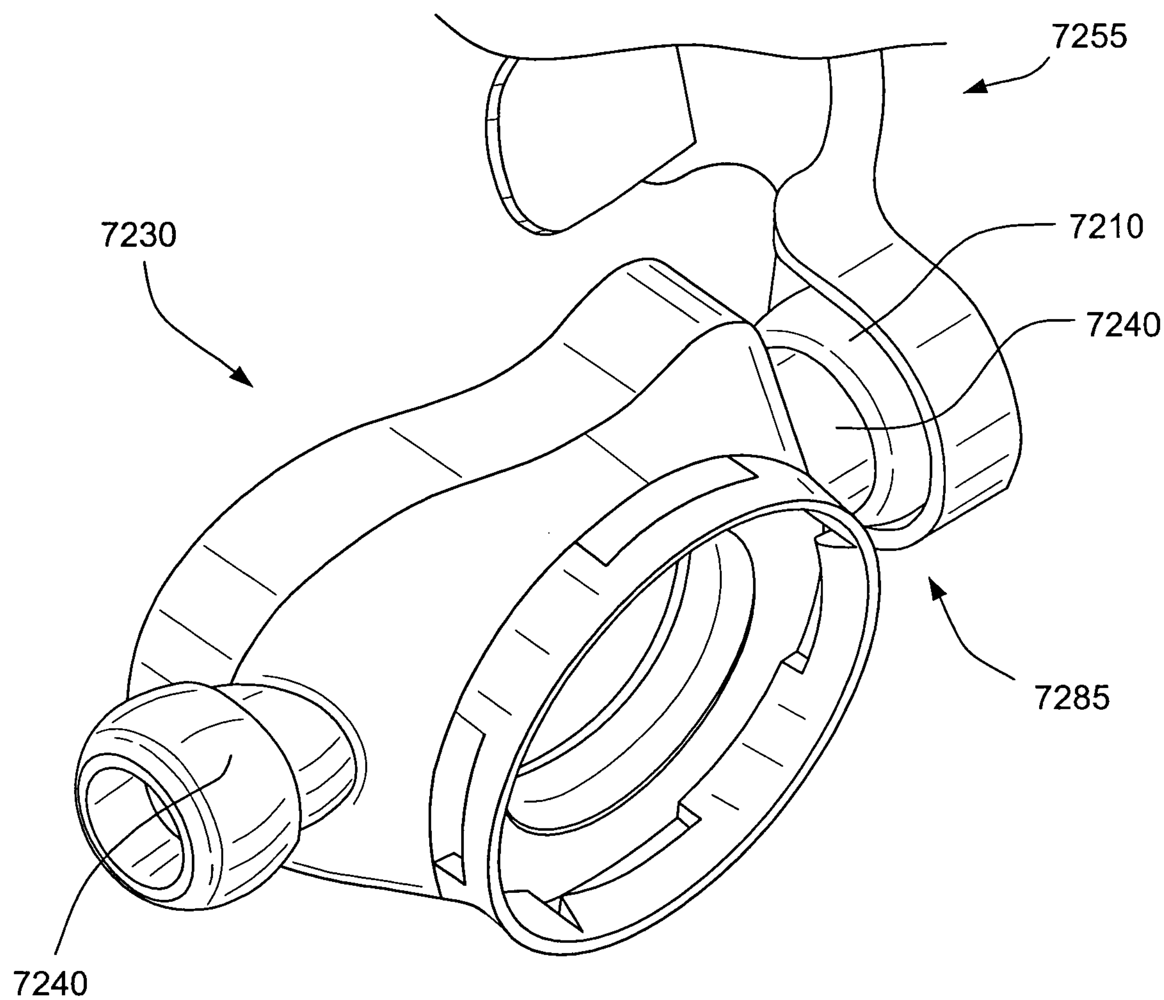


Fig. 22-24

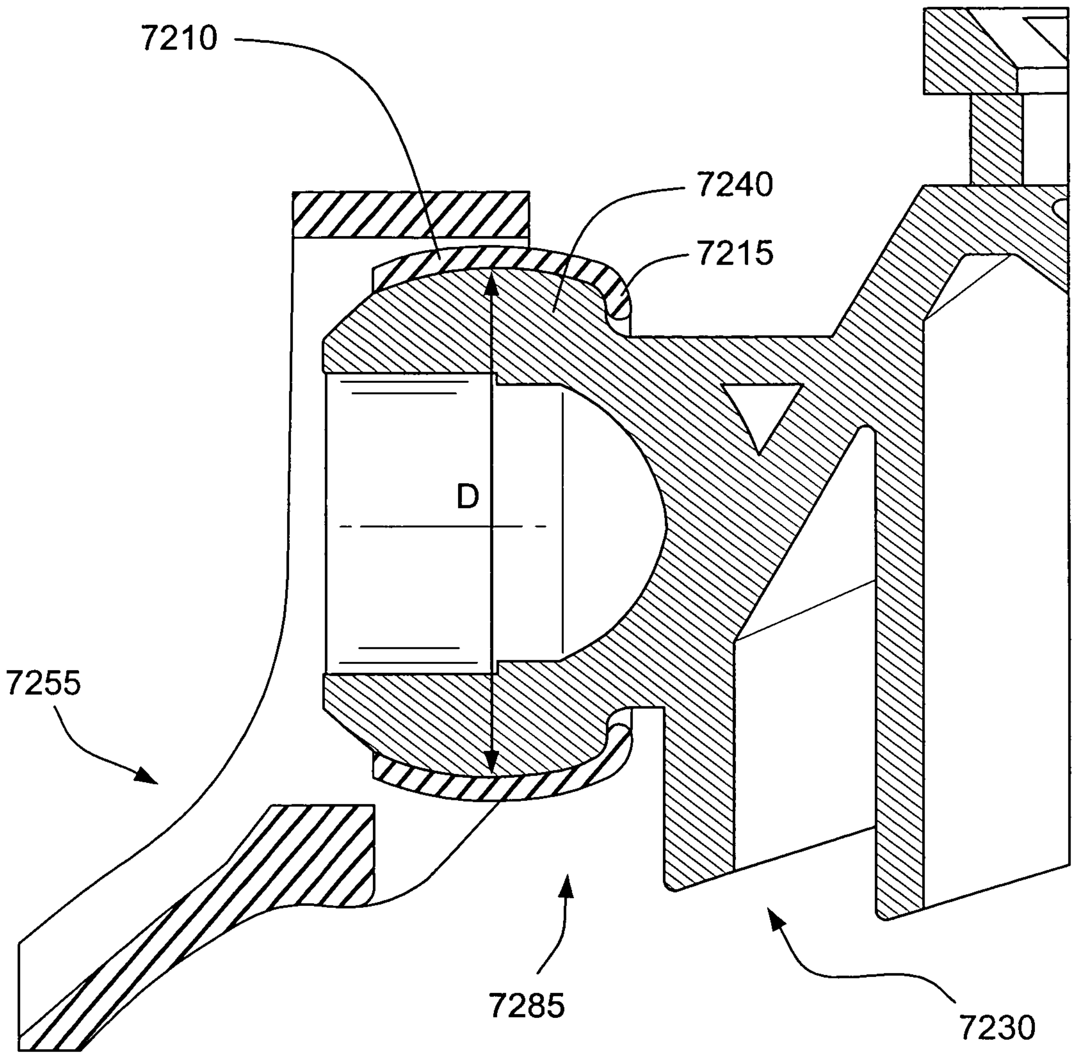


Fig. 22-25

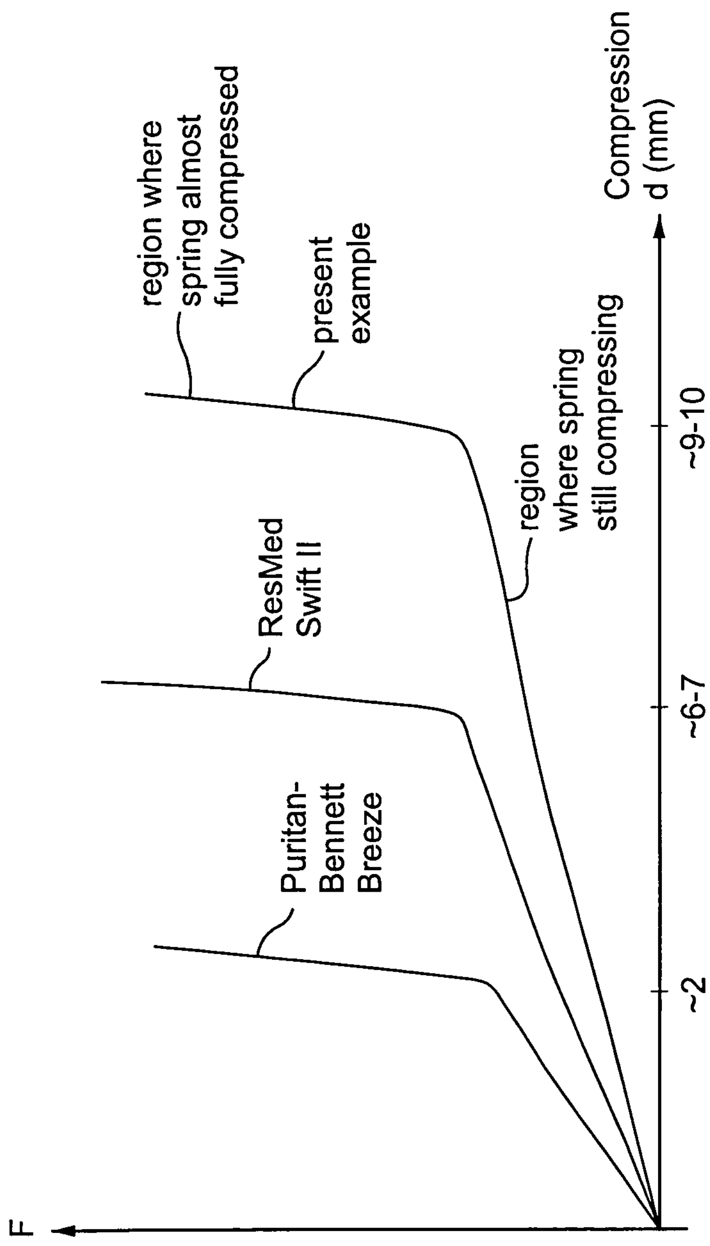

F
Compression
d (mm)
~2
~6-7
~9-10
Puritan-
Bennett
Breeze
ResMed
Swift II
region where
spring almost
fully compressed
present
example
region
where spring
still compressing

Fig. 23

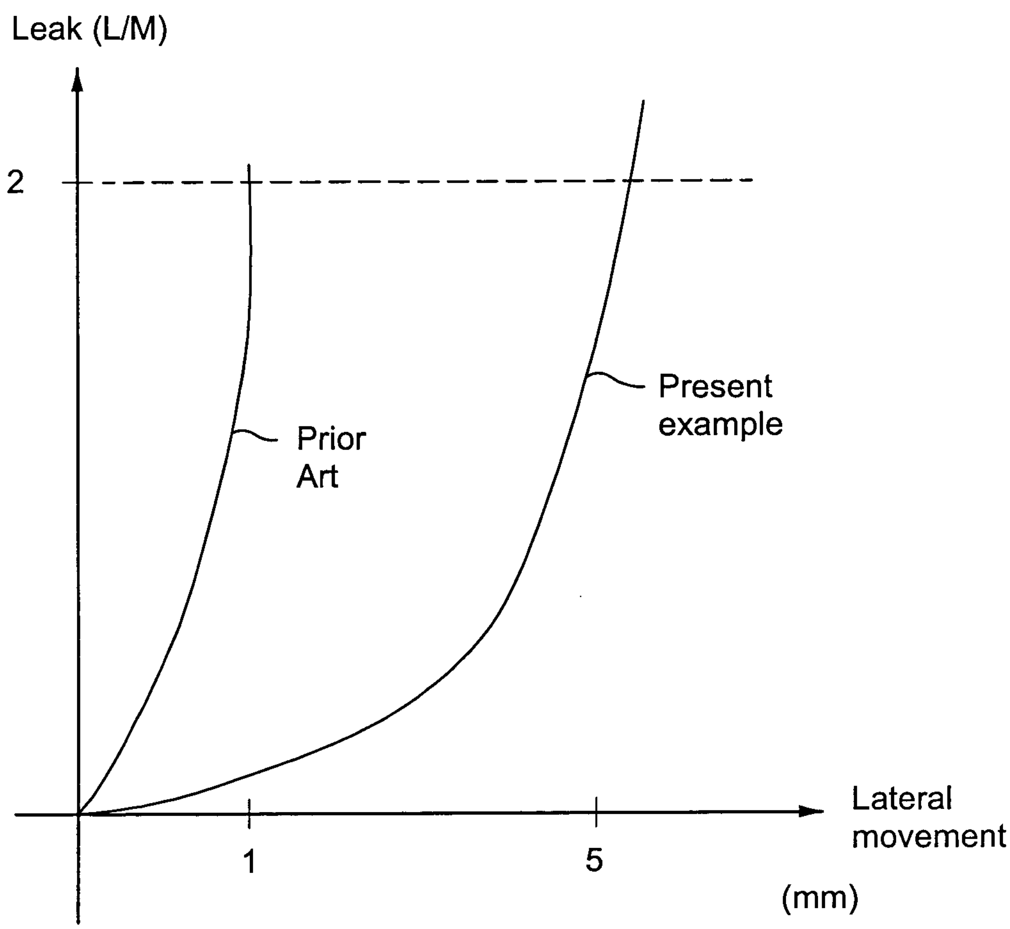


Fig. 24

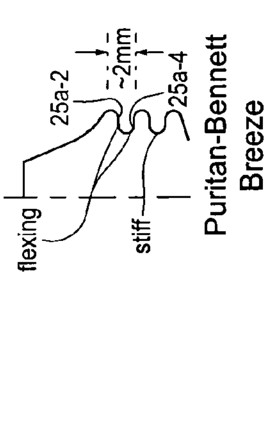


Fig. 25a

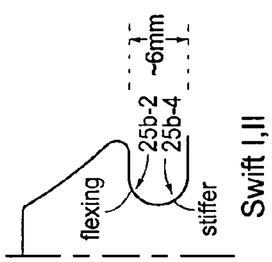


Fig. 25b

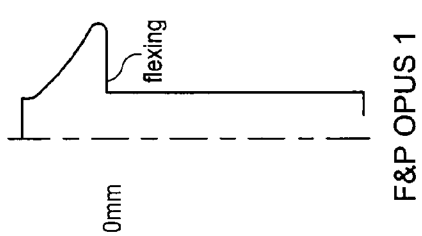


Fig. 25c

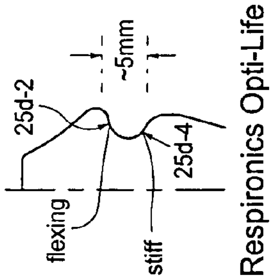


Fig. 25d

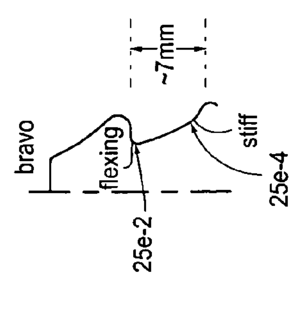


Fig. 25e

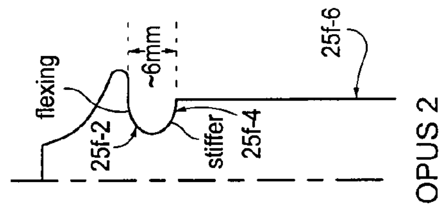


Fig. 25f

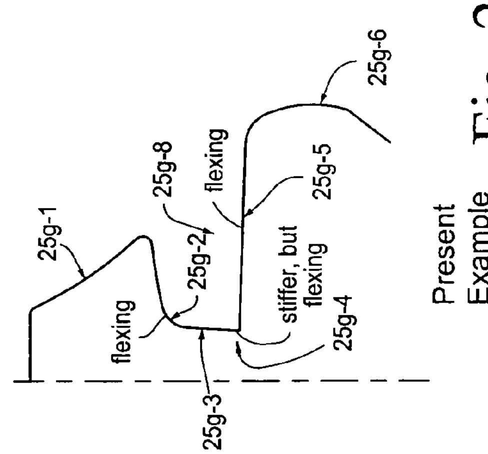


Fig. 25g

	Region name	SWIFT stiffness vs Present Example stiffness
1	Wall of pillow	>
2	Attachment of pillow to stalk	~=
3	Stalk	~=
4	Attachment of pillow to platform	<
5	Platform	>
6	Gusset/Base region	>>

Fig. 26

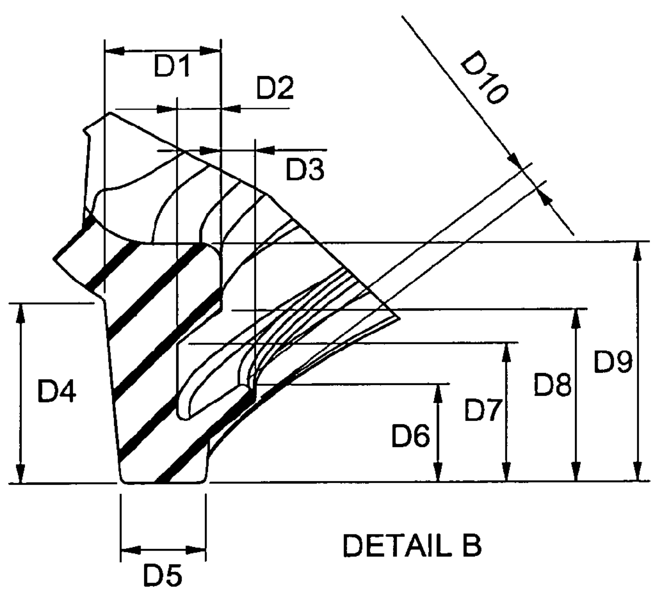


Fig. 27a

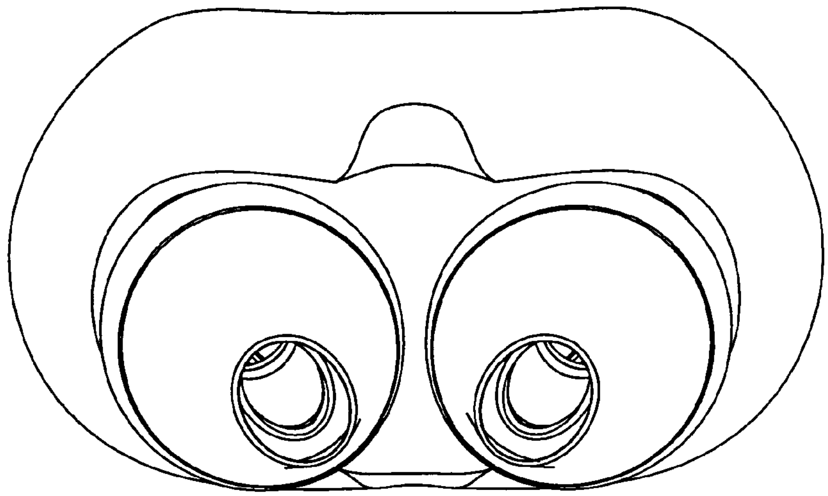


Fig. 27b

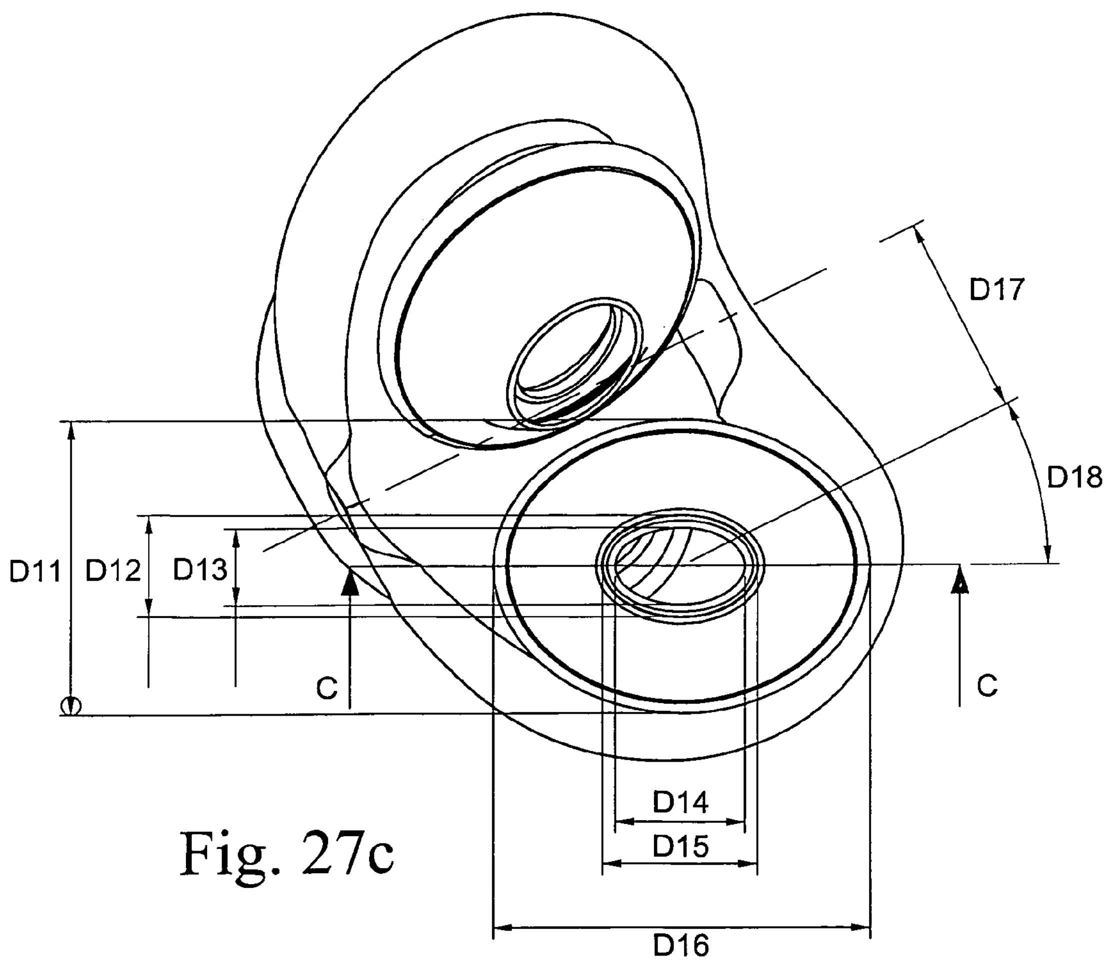


Fig. 27c

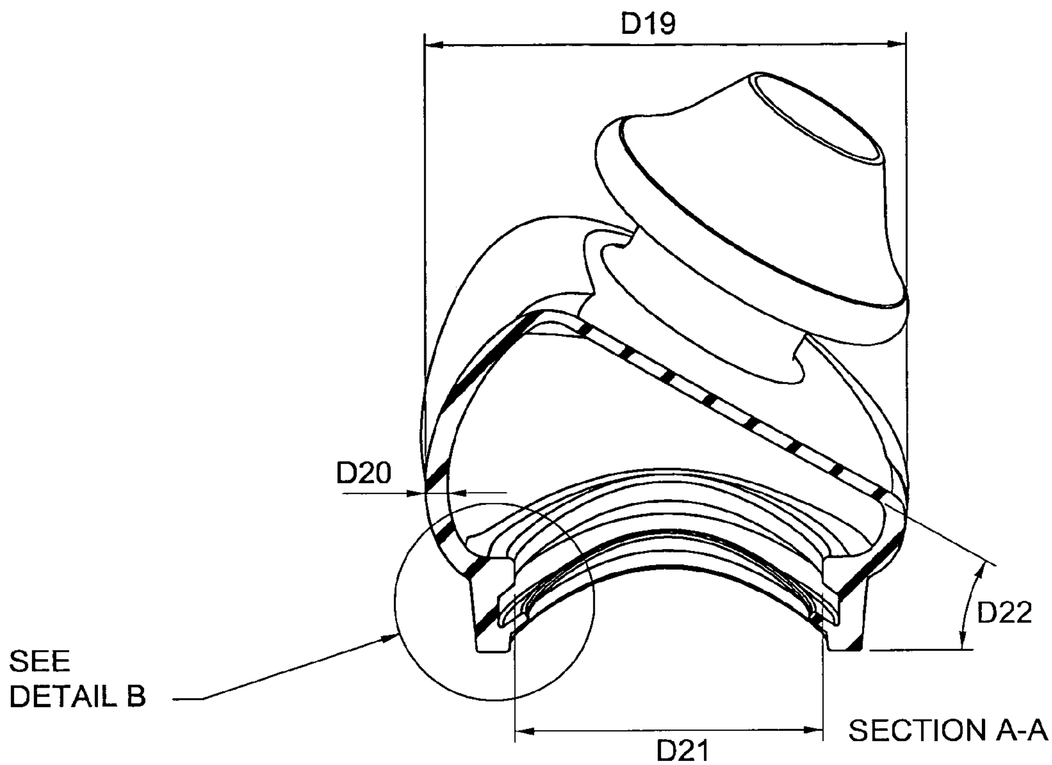


Fig. 27d

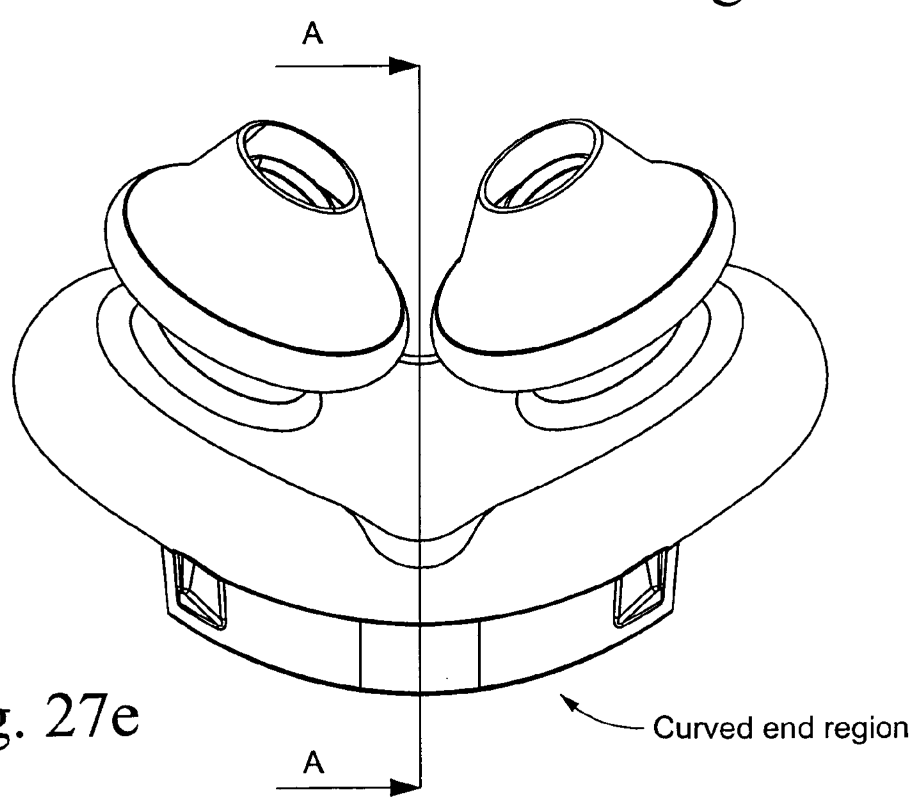


Fig. 27e

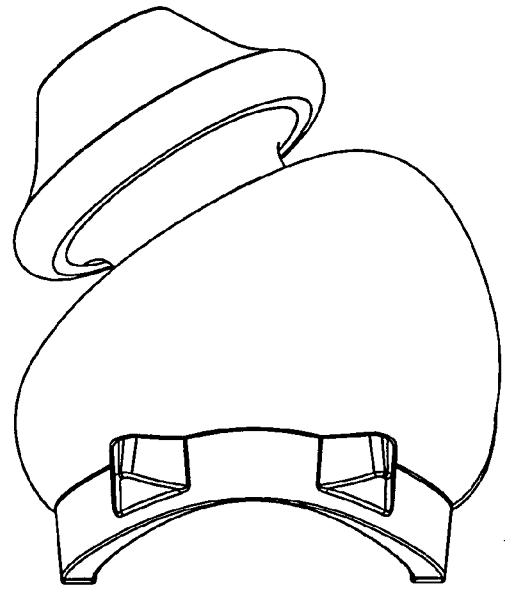


Fig. 27f

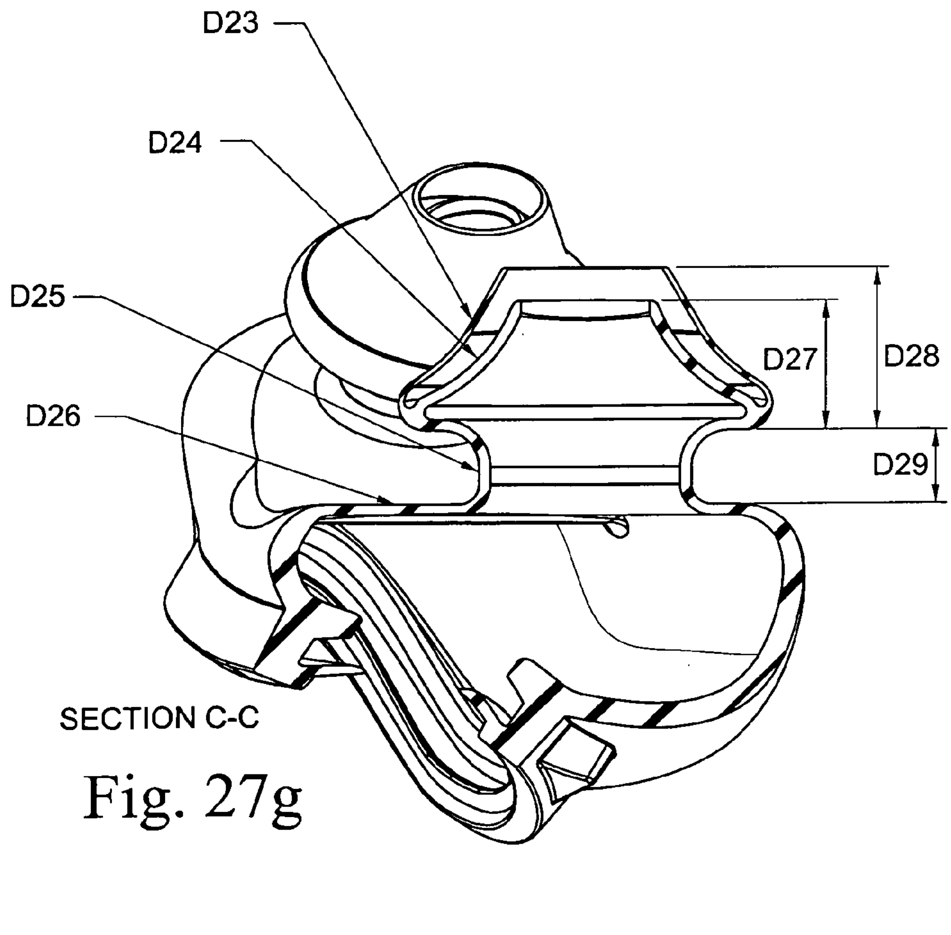


Fig. 27g

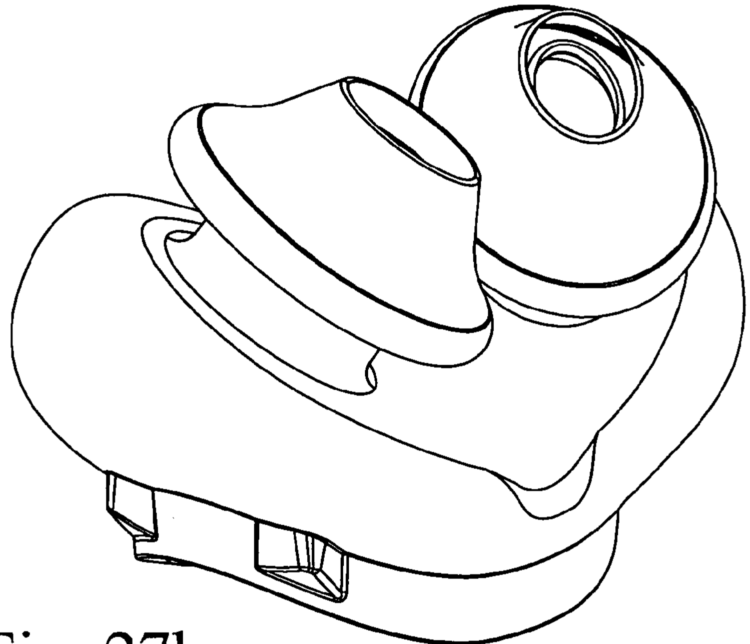


Fig. 27h

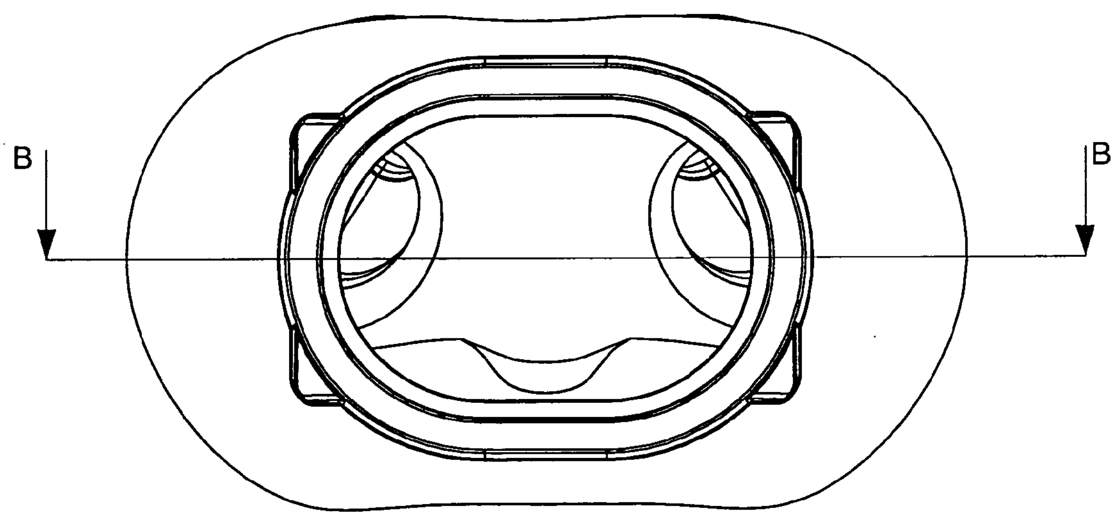


Fig. 27i

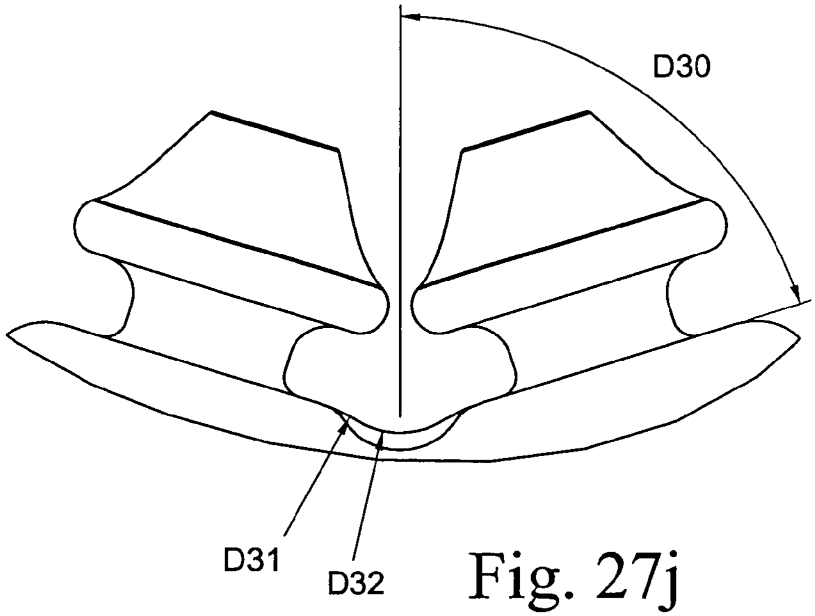


Fig. 27j

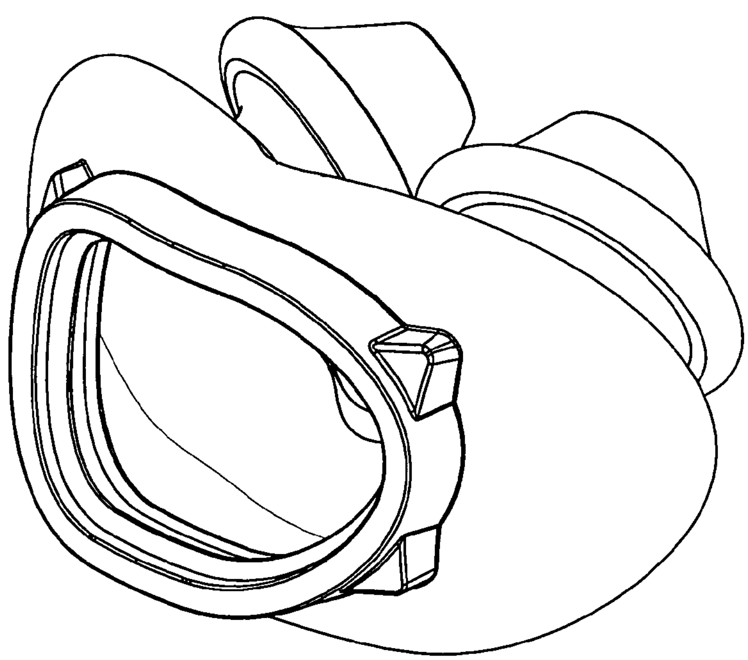
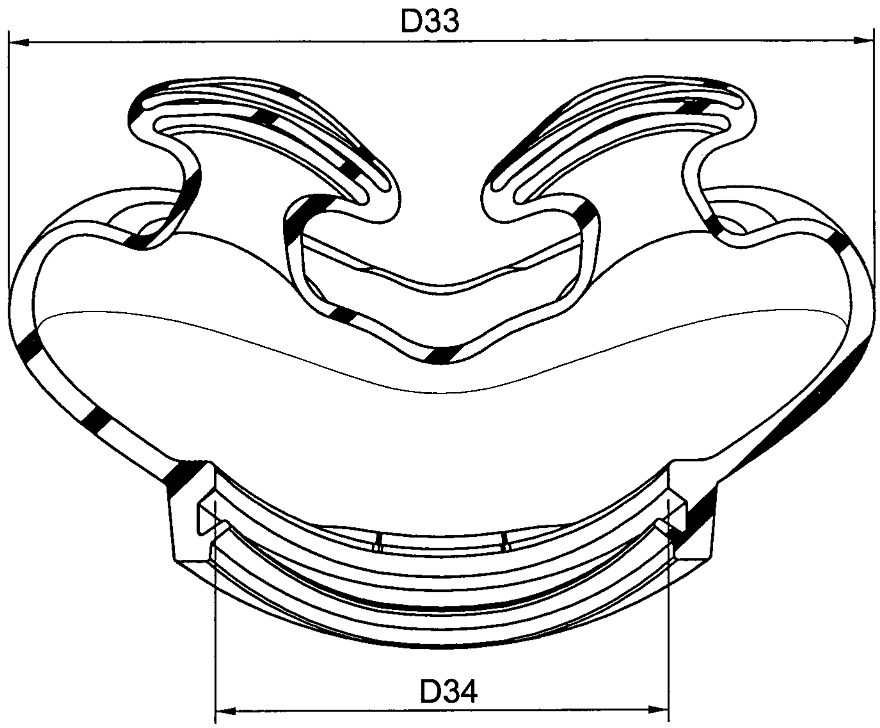


Fig. 27k



SECTION B-B

Fig. 271

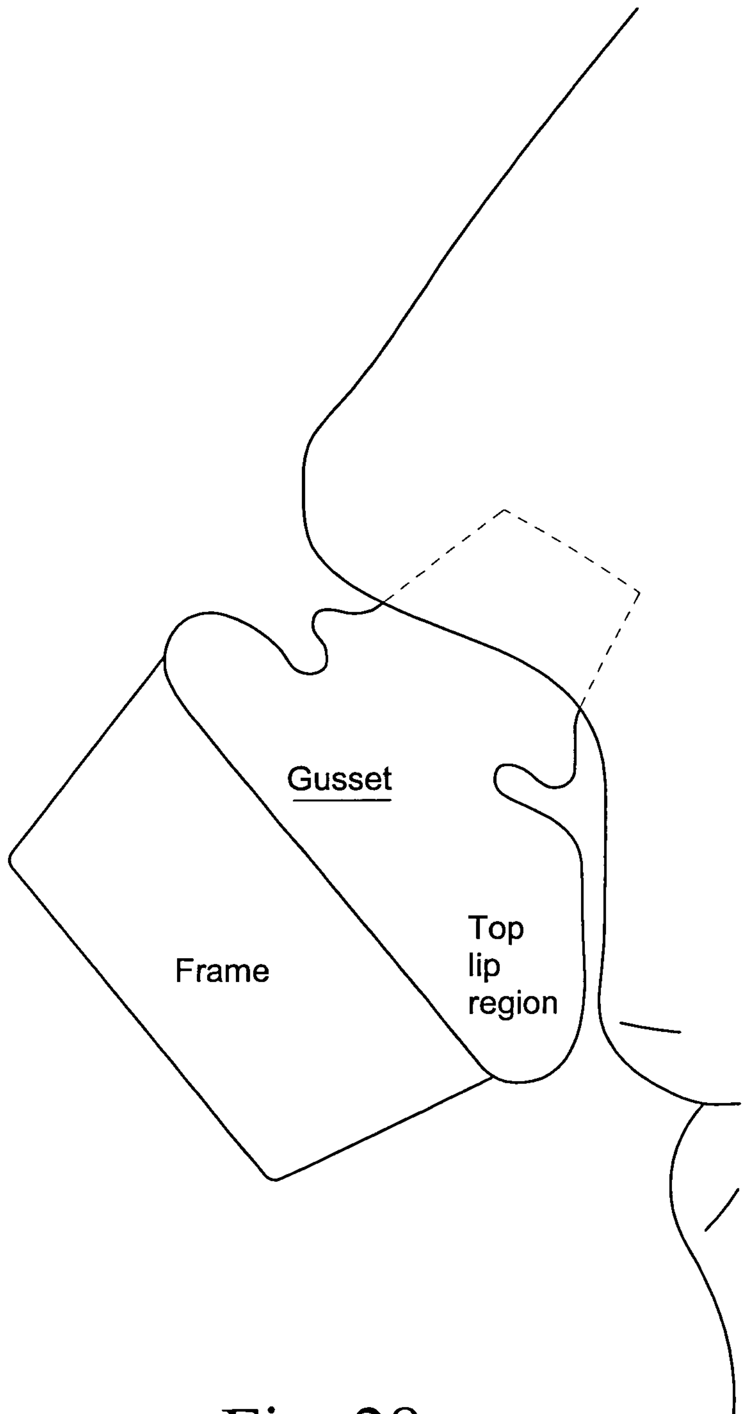


Fig. 28

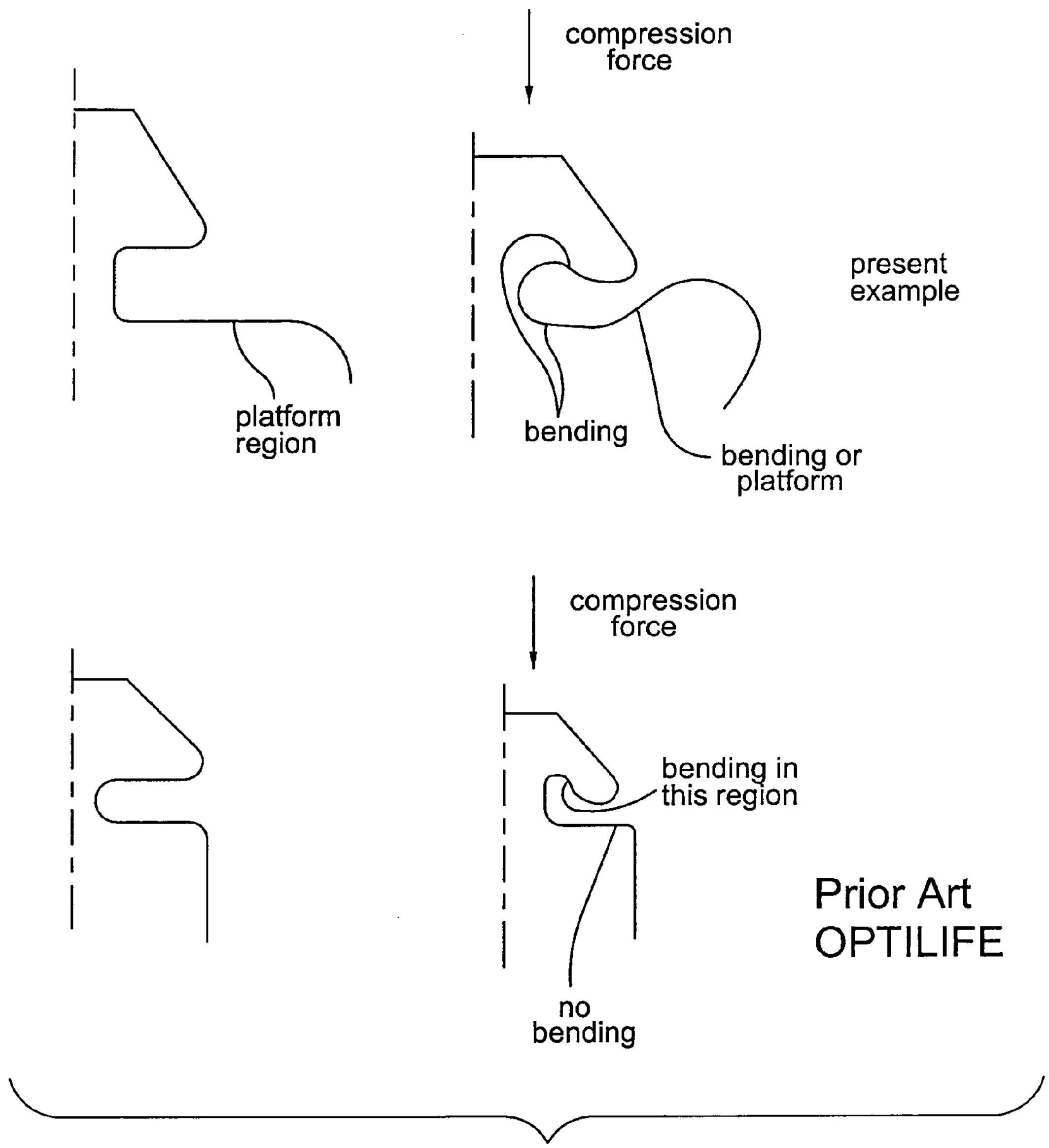

compression force
platform region
bending
bending or platform
present example
compression force
bending in this region
no bending
Prior Art OPTILIFE

Fig. 29

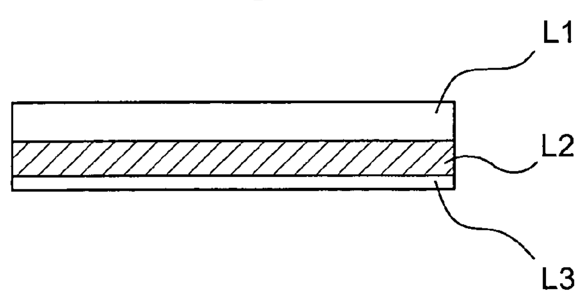

L1
L2
L3

Fig. 30

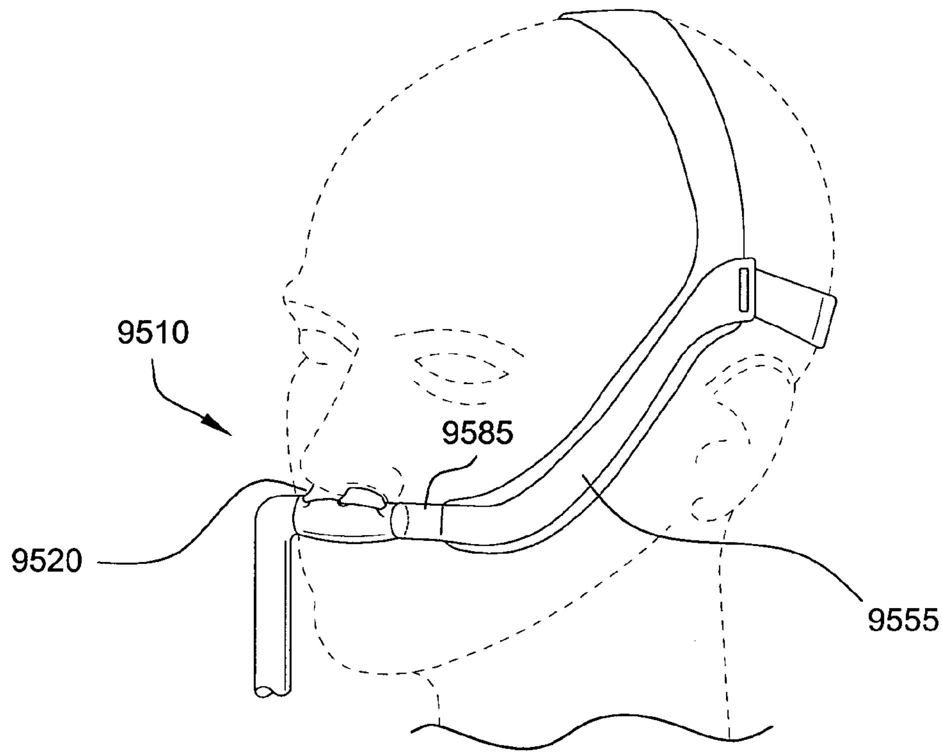


Fig. 31-1

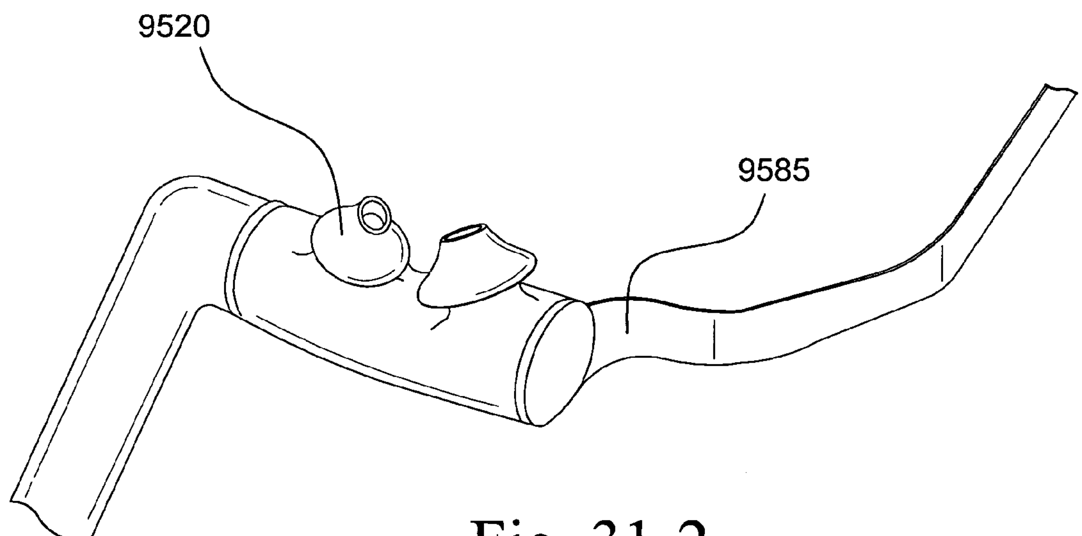


Fig. 31-2

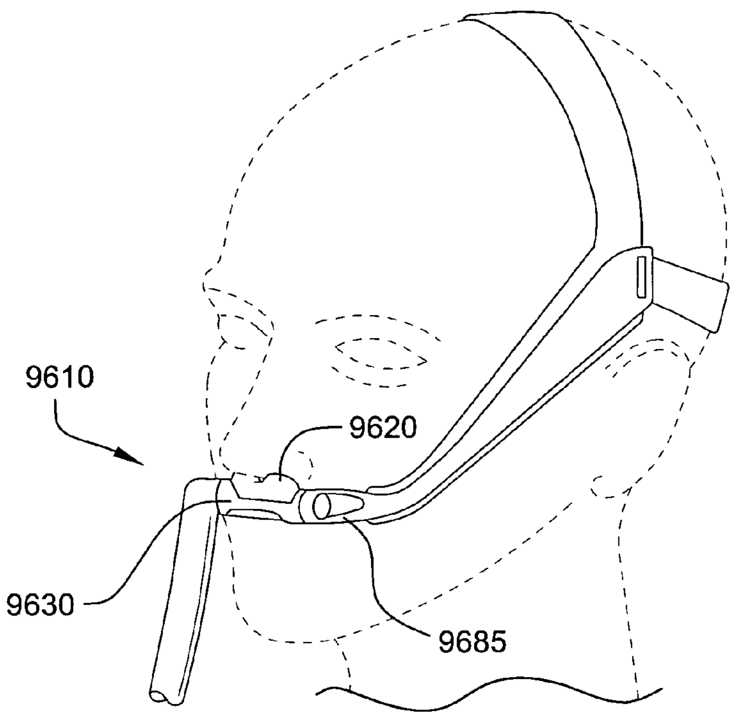


Fig. 32-1

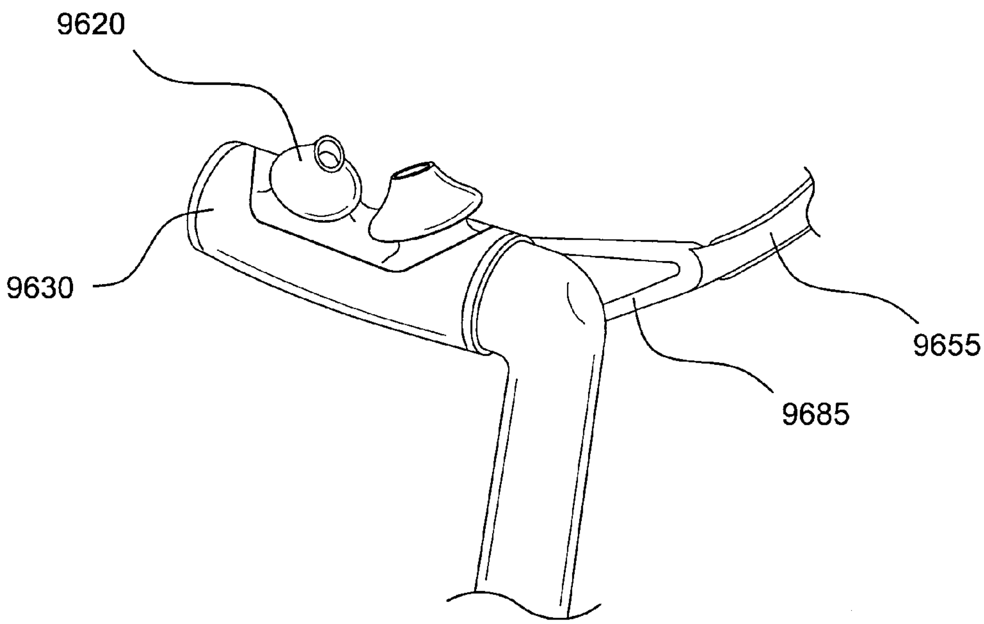


Fig. 32-2

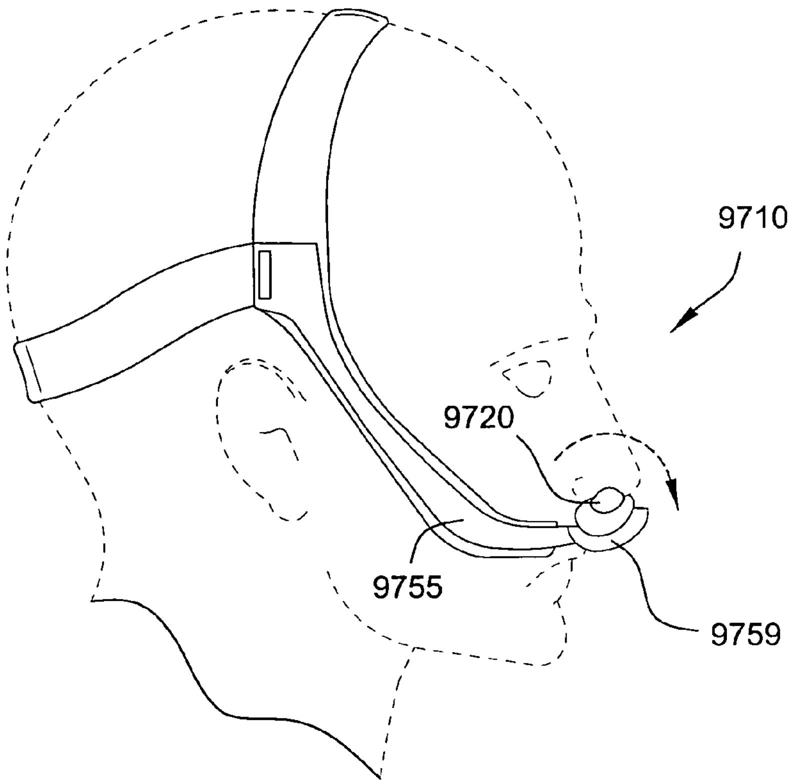


Fig. 33-1

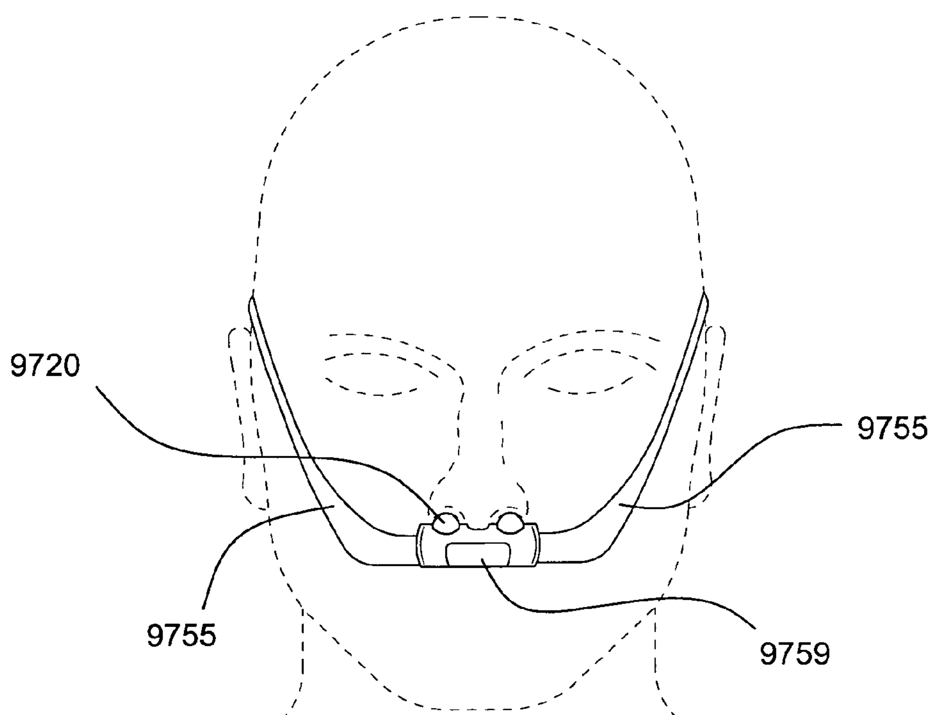


Fig. 33-2

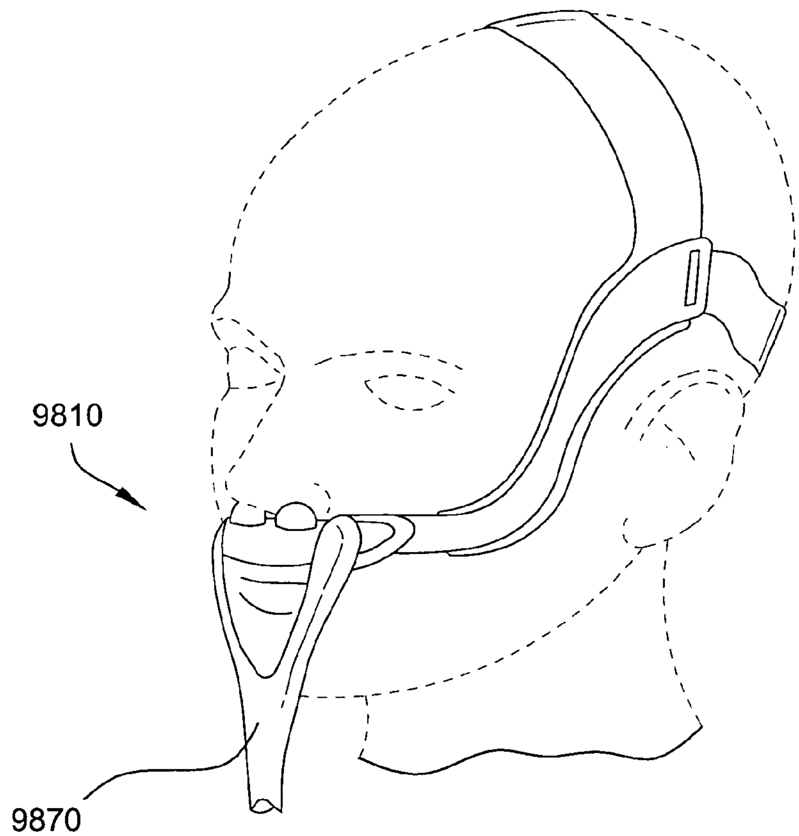


Fig. 34

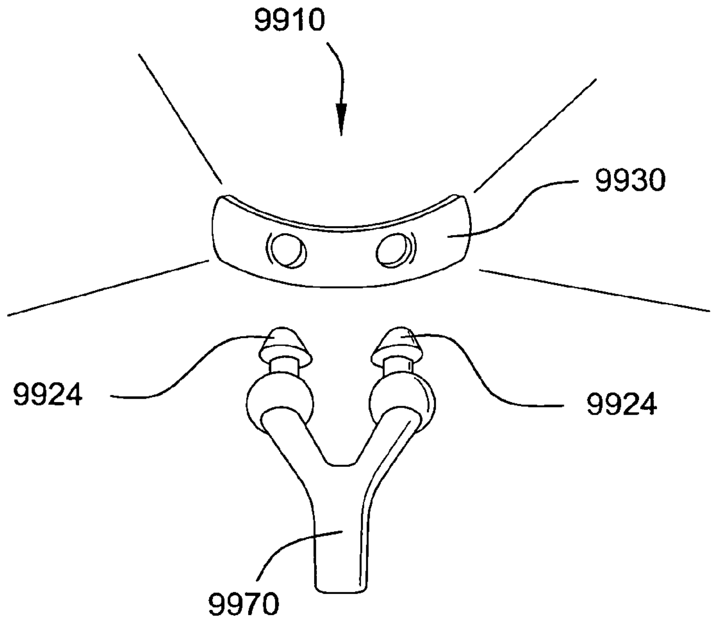


Fig. 35

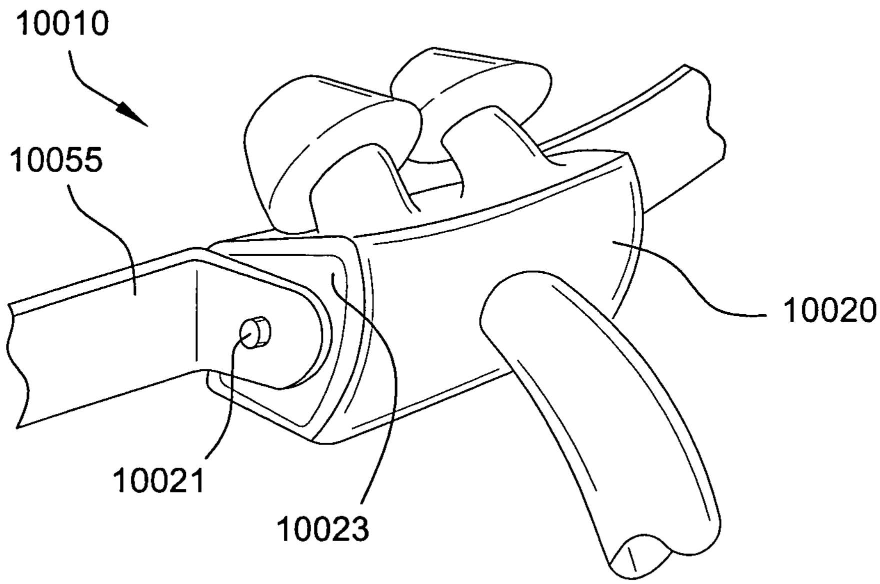


Fig. 36

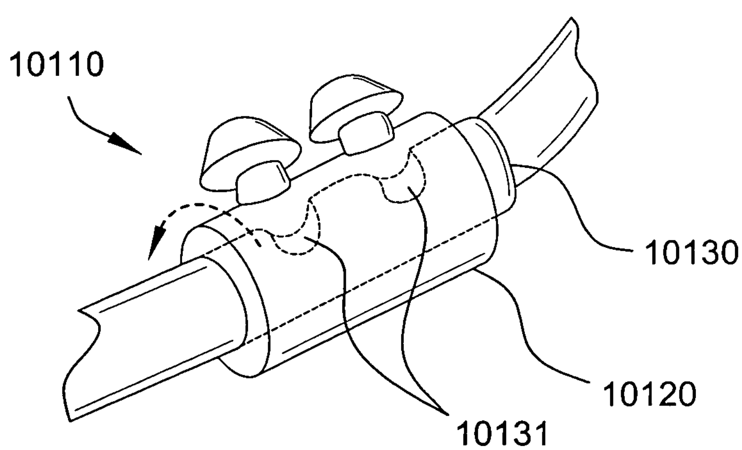


Fig. 37

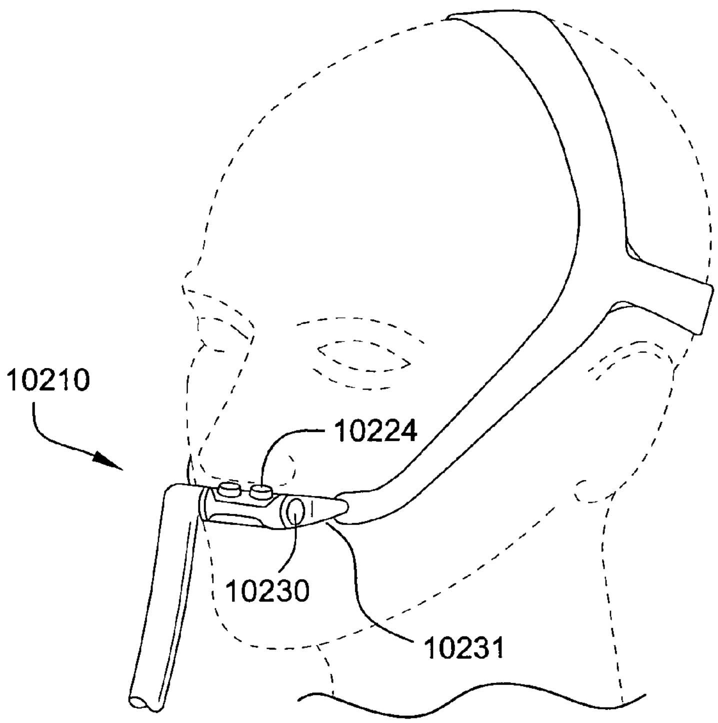


Fig. 38

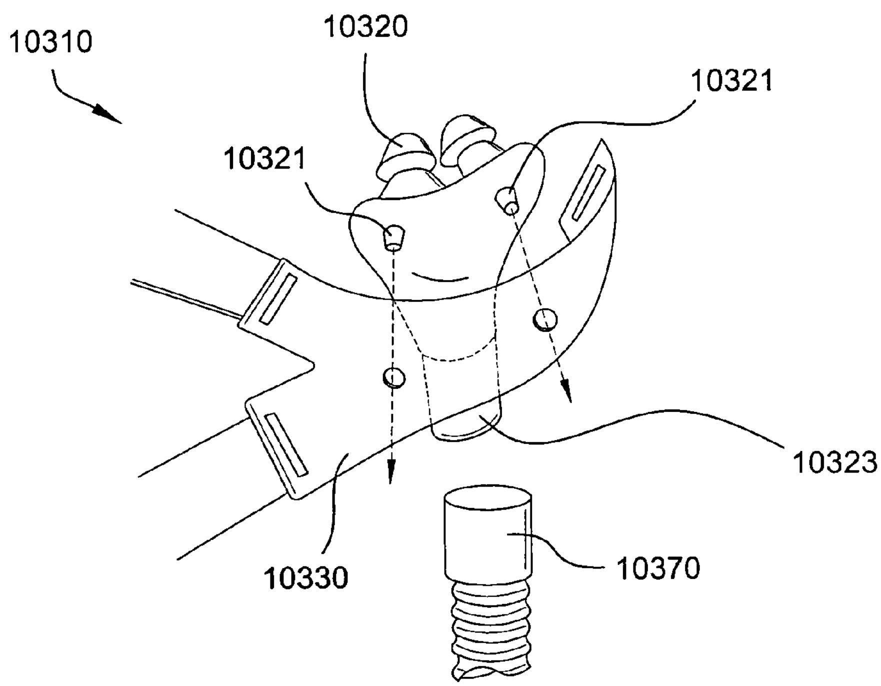


Fig. 39-1

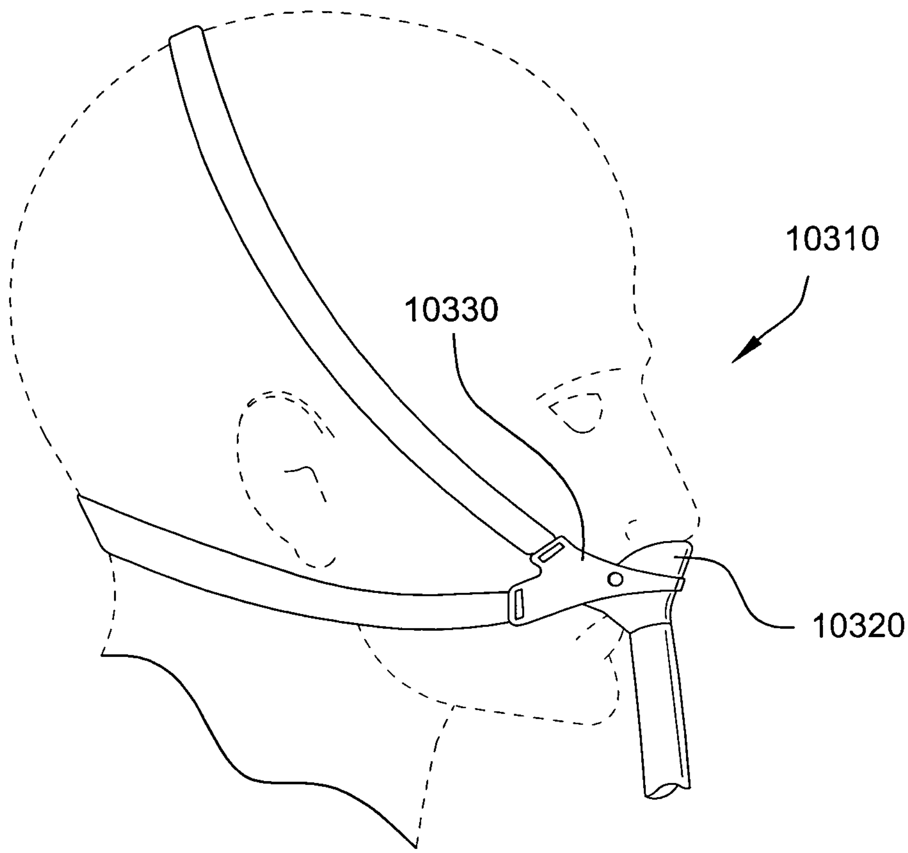


Fig. 39-2

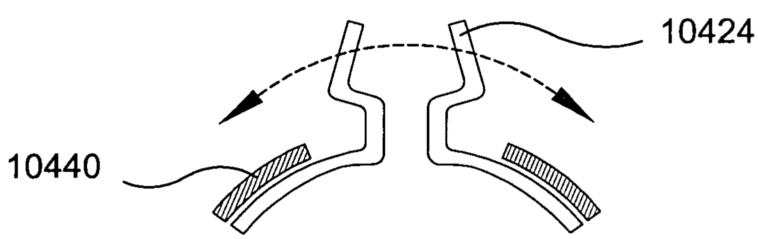


Fig. 40

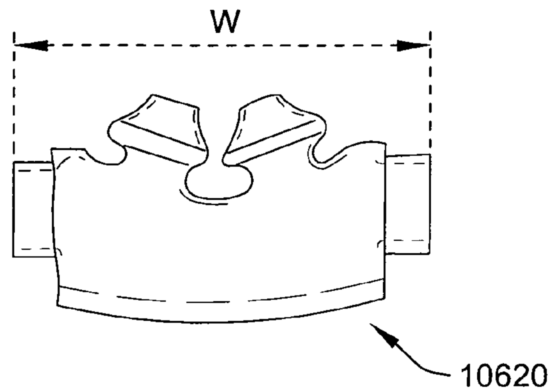


Fig. 41-1

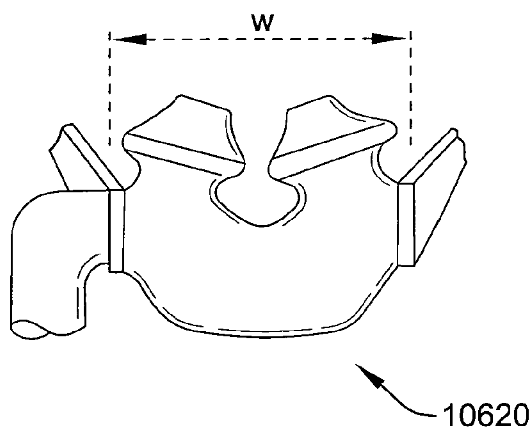


Fig. 41-2

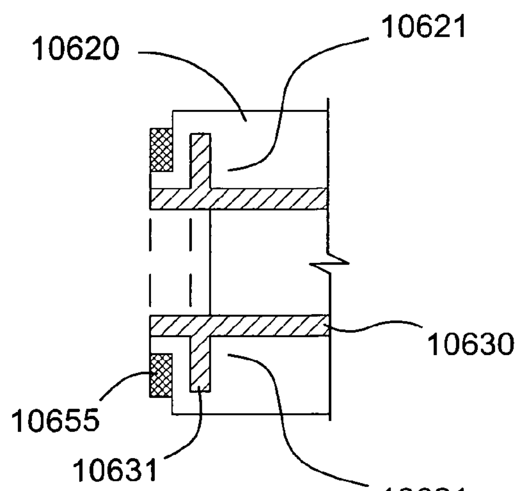


Fig. 41-3

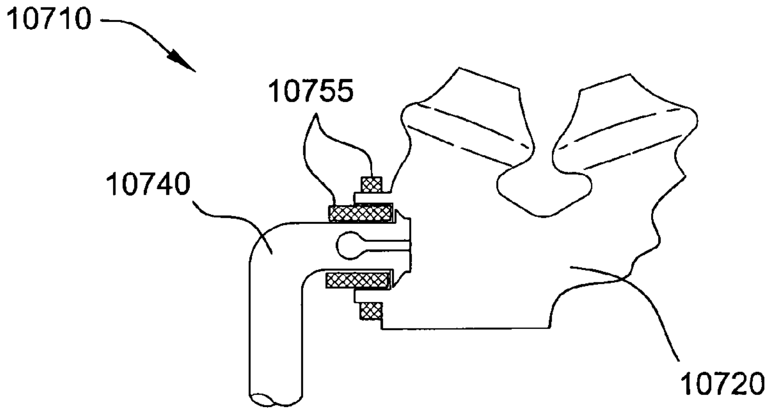


Fig. 42

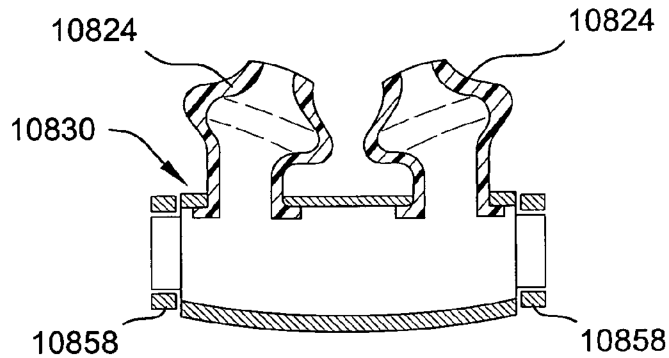


Fig. 43

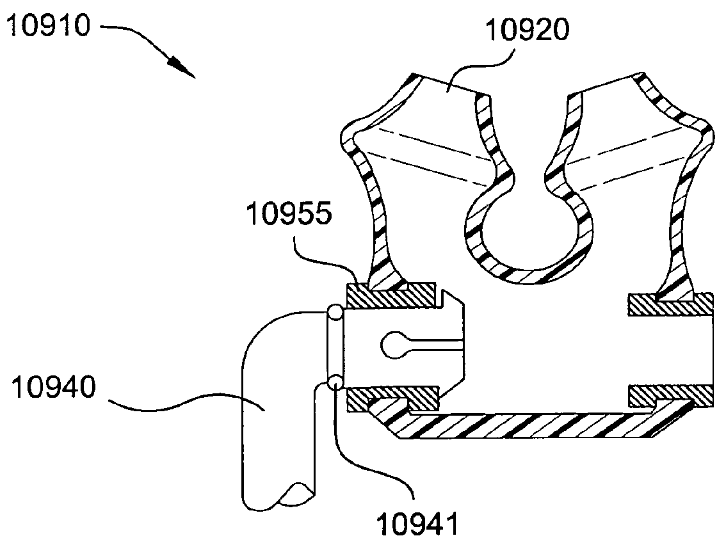


Fig. 44

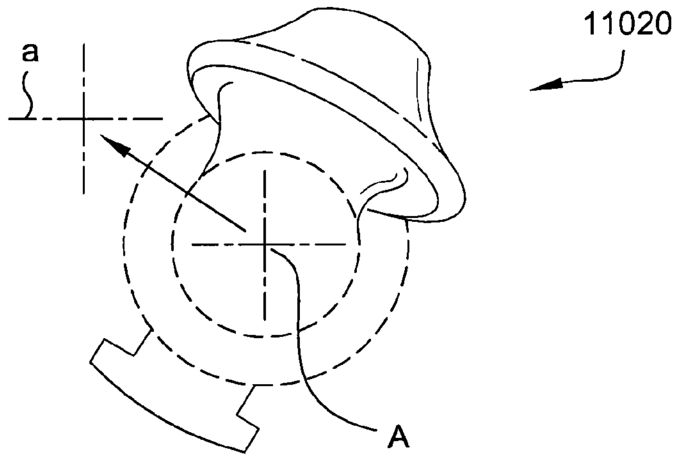


Fig. 45-1

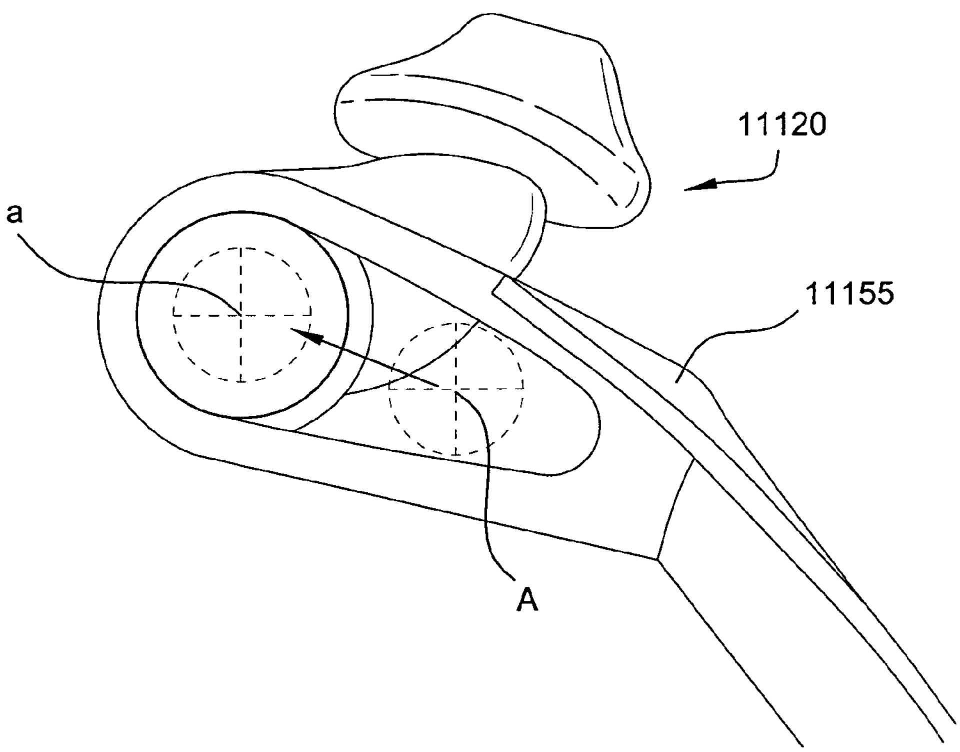


Fig. 45-2

PATIENT INTERFACE

CROSS-REFERENCE TO APPLICATION

This application claims the benefit of U.S. Provisional Application Nos. 60/935,179, filed Jul. 30, 2007, 60/996,160, filed Nov. 5, 2007, 61/006,409, filed Jan. 11, 2008, 61/064,818, filed Mar. 28, 2008, and 61/071,512, filed May 2, 2008, and Australian Provisional Application Nos. AU 2008900891, filed Feb. 25, 2008, AU 2008900134, filed Jan. 11, 2008, AU 2008900136, filed Jan. 11, 2008, AU 2008900137, filed Jan. 11, 2008, AU 2008900138, filed Jan. 11, 2008, AU 2008900139, filed Jan. 11, 2008, AU 2008900140, filed Jan. 11, 2008, and AU 2008900141, filed Jan. 11, 2008, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to a patient interface for delivery of respiratory therapy to a patient. Examples of such therapies are Continuous Positive Airway Pressure (CPAP) treatment, Non-Invasive Positive Pressure Ventilation (NIPPV), and Variable Positive Airway Pressure (VPAP). The therapy is used for treatment of various respiratory conditions including Sleep Disordered Breathing (SDB) such as Obstructive Sleep Apnea (OSA).

BACKGROUND OF THE INVENTION

Mask systems form an interface between a patient and apparatus providing a supply of pressurized air or breathing gas and are hence sometimes referred to as patient interfaces. In this specification, the words mask system and patient interface will be used interchangably. Mask systems in the field of the invention differ from mask systems used in other applications such as aviation and safety in particular because of their emphasis on comfort. This high level of comfort is desired because patients must sleep wearing the masks for hours, possibly each night for the rest of their lives. Mask systems typically, although not always, comprise (i) a rigid or semi-rigid portion often referred to as a shell or frame, (ii) a soft, patient contacting portion often referred to as a cushion, and (iii) some form of headgear to hold the frame and cushion in position. Mask systems often include a mechanism for connecting an air delivery conduit. The air delivery conduit is usually connected to a blower or flow generator.

A range of patient interfaces are known including nasal masks, nose & mouth masks, full face masks and nasal prongs, pillows, nozzles & cannulae. Masks typically cover more of the face than nasal prongs, pillows, nozzles and cannulae. In this specification, all will be collectively referred to as patient interfaces or mask systems. Nasal prongs, nasal pillows, nozzles and cannulae all will be collectively referred to as nasal prongs.

SUMMARY OF THE INVENTION

A first aspect of the invention relates to a patient interface for delivering breathable gas to a patient. A mask system in accordance with an embodiment of the invention provides improved seal, fit, comfort, stability, adjustability and ease of use compared to prior art mask systems. Other aspects of the invention include providing a small, lightweight, unobtrusive mask system. Another aspect is to provide a mask system that fits a wide range of different faces.

One aspect of improved seal is provided through the use of dual walled nasal pillows in accordance with an embodiment of the invention. Another aspect is the ability of a mask system in accordance with an embodiment of the invention to maintain a seal despite tube drag, side-sleeping, and other disruptions. Another aspect of improved seal and fit is through the adjustability provided by a mask in accordance with an embodiment of the invention which allows adjustment to better suit an individual patient's face.

A mask system in accordance with an embodiment of the invention is flexible and can fit a wide variety of facial shapes. An aspect of flexibility of a mask system in accordance with an embodiment of the invention is provided through the use of a semi-rigid frame. The use of a semi-rigid frame also leads to an improved seal with an elbow, and a reduction in the overall number of parts.

A mask system in accordance with an embodiment of the invention provides improved comfort through improved seal, meaning patients do not need to overtighten headgear straps to get a seal. Another aspect of improved comfort comes from removal of a rear buckle when compared to otherwise similar prior art mask systems. Another aspect of the invention providing improved comfort is through the improved attachment mechanism of stiffening portions of the interface stabilizing arrangement, for example, across the cheek regions. Another aspect of improved comfort of the present invention results from a more comfortable strap and or padding arrangement in the cheek region that leads to a reduction in "cheek mark" when compared to the prior art.

An aspect of improved stability provided to a mask in accordance with an embodiment of the invention is through support features that engage with the front of the face generally in the region of the maxilla and or zygoma, depending on the size of the patient's face.

An aspect of the present invention relates to a patient interface including a nasal prong assembly including a pair of nasal prongs structured to sealingly communicate with nasal passages of a patient's nose in use and headgear to maintain the nasal prong assembly in a desired position on the patient's face. The headgear includes side straps and rigidizers provided to respective side straps. Each rigidizer includes a first end portion that provides a connector structured to engage a respective end of the nasal prong assembly and a curved protrusion in the form of a cheek support that curves forward of the connector. The cheek support is adapted to follow the contour of the patient's cheek and guide a respective end portion of the side strap into engagement with the patient's cheek to provide a stable cheek support.

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient. The patient interface includes a nasal seal to sealingly communicate with the patient's nose in use and headgear to maintain the nasal seal in a desired position on the patient's face. The headgear includes side straps. Each side strap includes a curved protrusion in the form of a cheek support adapted to follow the contour of the patient's cheek and guide a respective end portion of the side strap into engagement with the patient's cheek to provide a stable cheek support.

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient. The patient interface includes a nasal seal to sealingly communicate with the patient's nose in use and headgear to maintain the nasal seal in a desired position on the patient's face. The headgear includes side straps each having a rigidizer with a slotted connector portion and a rear or back strap having ends that connect to a respective slotted connector portion.

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient. The patient interface includes a frame, a nasal prong assembly provided to the frame and adapted to provide an effective seal or interface with the patient's nose, an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and headgear adapted to support the patient interface in a desired position on the patient's head. The frame is relatively harder than the nasal prong assembly and relatively softer and more flexible than the elbow. In an embodiment, the frame is relatively softer and more flexible than the elbow and/or headgear yokes of the headgear. In an embodiment, the nasal prong assembly includes a gusset that allows a range of axial and lateral movement while maintaining a sufficient seal. In an embodiment, the headgear yoke of the headgear includes a yoke to frame interface structured to retain the headgear yoke to the frame, provide rotation relative to the frame, and provide a friction element to provide sufficient rotational torque (e.g., to reduce tube drag, to provide tactile/audible feedback).

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient. The patient interface includes a frame, a nasal prong assembly provided to the frame and adapted to provide an effective seal or interface with the patient's nose, an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and headgear adapted to support the patient interface in a desired position on the patient's head. The headgear includes side straps and rigidizers provided to respective side straps. Each rigidizer includes a frame interface structured to retain the rigidizer to the frame, provide rotation relative to the frame, and provide a friction element to provide sufficient rotational torque.

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient. The patient interface includes a pair of nasal prongs adapted to provide an effective seal or interface with the patient's nose and a support arrangement to support the nasal prongs in an operative position on the patient's face. The support arrangement is structured to provide a range of rotational, axial, and lateral movement to the nasal prongs while maintaining a sufficient seal and resisting the application of tube drag and headgear tension to the nasal prongs.

Another aspect of the invention relates to a headgear link member for connecting two or more straps of a headgear assembly for securing a respiratory mask to a patient. The link member is flexible and has connector portions for adjustable connection to said two or more straps.

Another aspect of the invention relates to a headgear assembly for securing a respiratory mask to a patient including a pair of rear headgear straps located in use at a rear portion of the patient's head and a headgear link member connecting the rear headgear straps. The straps and link member are configured such that each strap passes through the link member in a single U-shape and is secured back to itself.

Another aspect of the invention relates to headgear for a patient interface including a pair of side straps. Each of the side straps includes an upper strap portion adapted to pass over the top of the patient's head, a front strap portion adapted to pass along the side of the patient's head, and a rear strap portion adapted to pass around a rear portion of the patient's head. The free end of each rear strap portion includes a tab of hook material, and one side of each rear strap portion is coated with un-broken loop material which allows the tab of hook material to fasten anywhere along its length.

Another aspect of the invention relates to a patient interface for delivering breathable gas to a patient including a frame and a nasal prong assembly provided to the frame. The nasal prong assembly includes a pair of nasal prongs adapted to provide an effective seal or interface with the patient's nose. The nasal prong assembly includes a frame contacting portion that is adapted to be inserted and retained within a frame channel provided to the frame. The frame contacting portion includes an external protrusion that is adapted to protrude through a corresponding opening provided in the frame channel.

Another aspect of the invention relates to a tube retainer for retaining an air delivery tube to a headgear strap of headgear. The tube retainer includes a first strap portion adapted to loop around a headgear strap of headgear and a second strap portion provided to the first strap portion and adapted to loop around an air delivery tube. The first and second strap portions are integrally formed in one-piece from a soft and flexible material with the second strap portion extending transverse to the first strap portion. Each strap portion includes a hook and loop arrangement adapted to secure the respective strap portion in position.

Another aspect of the invention relates to a tube retaining assembly for retaining air delivery tubing including a headgear buckle including opposing locking portions adapted to be removably and adjustably coupled with respective headgear straps of headgear and a tube retainer provided to the headgear buckle. The tube retainer includes a pair of arcuate arms adapted to retain air delivery tubing.

Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

FIG. **1-1** is a perspective view of headgear for a patient interface according to an embodiment of the present invention;

FIGS. **2-1** and **2-2** are perspective views of a nasal prong assembly for a patient interface according to an embodiment of the present invention;

FIGS. **2-3** and **2-4** are top and front views of a nasal prong assembly for a patient interface and showing exemplary dimensions according to an embodiment of the present invention;

FIG. **3-1** is a perspective view of dual wall nasal prongs according to an embodiment of the present invention;

FIG. **4-1** is a schematic view of a trampoline-like suspension system for a nasal prong and showing exemplary dimensions according to an embodiment of the present invention;

FIG. **4-2** is a schematic view of a trampoline-like suspension system for a nasal prong according to another embodiment of the present invention;

FIGS. **5-1** to **5-40** illustrate nasal prongs and nasal prong assemblies according to alternative embodiments of the present invention;

FIG. **5-41** illustrates a nasal prong assembly and air delivery conduit according to another embodiment of the present invention;

FIG. **5-42-1** to **5-42-6** are various views of a tube retainer according to an embodiment of the present invention;

FIG. **5-43-1** to **5-43-7** are various views of a headgear buckle according to an embodiment of the present invention;

FIGS. **5-44-1** to **5-44-4** are respectively side, top, cross-section (along line **5-44-3** of FIG. **5-44-2**), and bottom orthogonal views of a link according to an embodiment of the present invention;

FIG. **5-44-5** is an isometric view of the link shown in FIGS. **5-44-1** to **5-44-4**;

FIG. **5-45** is a cross-section showing the connection between the headgear straps and the link shown in FIGS. **5-44-1** to **5-44-4**;

FIG. **5-46** shows a portion of a prior art headgear buckle and strap assembly in use;

FIGS. **5-47-1** to **5-47-6** are various views of a tube retainer according to an embodiment of the present invention;

FIG. **5-48** is an isometric view of a buckle according to an embodiment of the present invention;

FIG. **5-49** is an isometric view of a buckle according to another embodiment of the present invention;

FIG. **5-50** is a side view of a buckle according to another embodiment of the present invention;

FIG. **5-51** is a side view of a buckle according to another embodiment of the present invention;

FIG. **5-52** is an isometric view of a buckle according to another embodiment of the present invention;

FIG. **5-53** is an isometric view of a buckle according to another embodiment of the present invention;

FIG. **5-54** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-55** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-56** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-57** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-58** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-59** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-60** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-61** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-62** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-63** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-64** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-65** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-66** is an isometric view of the keyhole of a buckle according to an embodiment of the present invention;

FIG. **5-67** is a top view of a buckle according to another embodiment of the present invention;

FIG. **5-68** is an isometric view of a tube retainer according to an embodiment of the present invention;

FIG. **5-69** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-70** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-71** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-72** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-73** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-74** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-75** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-76** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-77** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-78** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-79** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-80** is a front view of a tube retainer according to another embodiment of the present invention;

FIG. **5-81** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-82** is an isometric view of a tube retainer according to another embodiment of the present invention;

FIG. **5-83** is an isometric view of the tab of a tube retainer according to an embodiment of the present invention;

FIG. **5-84** is an isometric view of the tab of a tube retainer according to another embodiment of the present invention;

FIG. **5-85** is an isometric view of the tab of a tube retainer according to another embodiment of the present invention;

FIG. **5-86** is an isometric view of the tab of a tube retainer according to another embodiment of the present invention;

FIGS. **6-1** to **6-5** illustrate headgear yoke for headgear according to an embodiment of the present invention;

FIG. **7-1** schematically illustrates headgear tension on ResMed's Mirage Swift headgear;

FIG. **7-2** schematically illustrates headgear tension on headgear according to an embodiment of the present invention;

FIGS. **8-1** to **8-4** schematically illustrate headgear yoke according to alternative embodiments of the present invention;

FIG. **9** illustrates a rear strap for headgear according to an embodiment of the present invention;

FIGS. **10-1** illustrates a headgear strap section including a headgear strap and headgear yoke according to an embodiment of the present invention;

FIGS. **10-2-1** and **10-2-2** illustrate foam headgear straps according to an embodiment of the present invention;

FIG. **10-3-1** illustrates a cheek mark region with respect to ResMed's Swift headgear;

FIG. **10-3-2** illustrates a known headgear strap section;

FIG. **10-4** illustrates a headgear strap section according to an embodiment of the present invention;

FIGS. **10-5** and **10-6** illustrate headgear straps and headgear yokes according to alternative embodiments of the present invention;

FIGS. **10-7-1** to **10-7-3** illustrate headgear including a friction pad according to an embodiment of the present invention;

FIGS. **10-8-1** to **10-8-3** illustrate a nasal prong assembly including wings according to an embodiment of the present invention;

FIGS. **10-9-1** to **10-9-3** illustrate headgear including foam padding according to an embodiment of the present invention;

FIG. **10-9-4** illustrates headgear with yoke and wing without foam padding according to another embodiment of the present invention;

FIGS. **11-1** and **11-2** illustrate cutting profiles for headgear straps according to embodiments of the present invention;

FIGS. **12-1** to **12-26-2** illustrate headgear according to alternative embodiments of the present invention;

FIGS. **13-1** to **13-4** illustrate various views of a patient interface on a patient's head according to an embodiment of the present invention;

FIG. **13-5** is a schematic view illustrating headgear vectors according to an embodiment of the present invention;

FIGS. **14-1** to **14-2** illustrate various views of the patient interface shown in FIGS. **13-1** to **13-4** with the headgear straps removed;

FIGS. **15-1** to **15-12** illustrate various views of the frame of the patient interface shown in FIGS. **13-1** to **13-4**;

FIGS. **16-1** to **16-12** illustrate various views of the nasal prong assembly of the patient interface shown in FIGS. **13-1** to **13-4**;

FIGS. **16-13-1** to **16-13-7** illustrate a nasal prong assembly according to an embodiment of the present invention;

FIG. **16-14-1** illustrates an assembled view of a nasal prong assembly and frame according to another embodiment of the present invention;

FIG. **16-14-2** illustrates an unassembled view of the nasal prong assembly and frame shown in FIG. **16-14-1**;

FIG. **16-14-3** is a perspective view of a patient interface including the nasal prong assembly and frame of FIG. **16-14-1**;

FIGS. **16-15-1** to **16-15-10** illustrate various views of the nasal prong assembly of FIG. **16-14-1**;

FIGS. **16-16-1** to **16-16-8** illustrate various views of the frame of FIG. **16-14-1**;

FIG. **16-17** is a perspective view of a nasal prong assembly and frame according to another embodiment of the present invention;

FIG. **16-18-1** is a perspective view of a nasal prong assembly and frame according to another embodiment of the present invention;

FIG. **16-18-2** illustrates an unassembled view of the nasal prong assembly and frame shown in FIG. **16-18-1**;

FIG. **16-18-3** illustrates a frame according to an embodiment of the present invention;

FIG. **16-19** is a perspective view of a nasal prong assembly and frame according to another embodiment of the present invention;

FIG. **16-20** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to an embodiment of the present invention;

FIG. **16-21** is a cross-sectional view of a frame according to an embodiment of the present invention;

FIG. **16-22** is a cross-sectional view of a frame according to another embodiment of the present invention;

FIG. **16-23** is a cross-sectional view of a frame according to another embodiment of the present invention;

FIG. **16-24** is a cross-sectional view of a frame according to another embodiment of the present invention;

FIG. **16-25** is a cross-sectional view of a frame contacting portion of a nasal prong assembly according to an embodiment of the present invention;

FIG. **16-26** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to an embodiment of the present invention;

FIG. **16-27** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-28** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-29** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-30** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-31** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-32** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-33** is a cross-sectional view of a frame contacting portion of a nasal prong assembly and a frame according to another embodiment of the present invention;

FIG. **16-34-1** is a cross-sectional view of a frame contacting portion of a nasal prong assembly according to an embodiment of the present invention;

FIG. **16-34-2** is a cross-sectional view of a frame contacting portion of a nasal prong assembly according to an embodiment of the present invention;

FIG. **16-35** is a rear view of a frame and frame channel according to an embodiment of the present invention;

FIG. **16-36** is a rear view of a frame and frame channel according to another embodiment of the present invention;

FIG. **16-37** is a perspective view of a nasal prong assembly including a frame contacting portion according to an embodiment of the present invention;

FIG. **16-38** is a rear view of a frame and frame channel according to another embodiment of the present invention;

FIG. **16-39** is a cross-sectional view of a frame contacting portion of a nasal prong assembly according to another embodiment of the present invention;

FIG. **17** is a cross-sectional view of the patient interface shown in FIGS. **13-1** to **13-4**;

FIGS. **18-1** to **18-7** illustrate various views of the elbow of the patient interface shown in FIGS. **13-1** to **13-4**;

FIGS. **18-8-1** to **18-8-9** illustrate various views of an elbow according to another embodiment of the present invention;

FIG. **18-8-10** is a cross-sectional view through line **18-8-10-18-8-10** of FIG. **18-8-5**;

FIG. **18-8-11** is an enlarged portion of FIG. **18-8-10**;

FIG. **18-8-12** is a cross-sectional view through line **18-8-12-18-8-12** of FIG. **18-8-10**;

FIG. **18-8-13** is an enlarged portion of FIG. **18-8-12**;

FIG. **18-8-14** is a cross-sectional view similar to FIG. **18-8-10** in perspective;

FIG. **18-8-15** is an enlarged portion of FIG. **18-8-14**;

FIG. **18-8-16** shows the elbow attached to the frame and nasal prong assembly according to an embodiment of the present invention;

FIG. **18-8-17** shows the interface between the elbow and the short tube according to an embodiment of the present invention;

FIGS. **18-9-1** to **18-9-3** are various views of an elbow to frame attachment according to an embodiment of the present invention;

FIGS. **18-10-1** to **18-10-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-11-1** to **18-11-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-12-1** to **18-12-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-13-1** to **18-13-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-14-1** to **18-14-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-15-1** to **18-15-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-16-1** to **18-16-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-17-1** to **18-17-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **18-18-1** to **18-18-3** are various views of an elbow to frame attachment according to another embodiment of the present invention;

FIGS. **19-1** to **19-5** illustrate various views of headgear yoke of the patient interface shown in FIGS. **13-1** to **13-4**;

FIGS. **19-6** and **19-7** are enlarged views of the yoke to frame interface of the headgear yoke shown in FIGS. **19-1** to **19-5**;

FIG. **19-8** is a cross-sectional view illustrating the yoke to frame interface attached to a respective frame connector according to an embodiment of the present invention;

FIGS. **19-9-1** to **19-9-6** are sequential views illustrating attachment of the yoke to frame interface to a respective frame connector according to an embodiment of the present invention;

FIGS. **19-10** to **19-13** illustrate exemplary dimensions of the headgear yoke according to an embodiment of the present invention;

FIG. **19-14** is a side view illustrating rotational movement of the patient interface according to an embodiment of the present invention;

FIGS. **19-15-1** to **19-15-5** are sequential views illustrating rotational adjustment of the headgear yoke with respect to the frame according to an embodiment of the present invention;

FIG. **19-16** is a top view of the patient interface on a patient's head according to an embodiment of the present invention;

FIG. **19-17-1** to **19-17-4** illustrate various cross-sections through the headgear yoke according to an embodiment of the present invention;

FIG. **19-18** is a perspective view of the patient interface showing exemplary dimensions according to an embodiment of the present invention;

FIG. **19-19** is a cross-sectional view of the headgear yoke showing exemplary dimensions according to an embodiment of the present invention;

FIG. **19-20** is a cross-sectional view illustrating headgear yoke attached to a headgear strap according to an embodiment of the present invention;

FIGS. **19-21-1** to **19-21-3** illustrate a yoke to frame rotation indicator according to an embodiment of the present invention;

FIGS. **19-22-1** to **19-22-4** illustrate a yoke to frame rotation indicator according to another embodiment of the present invention;

FIGS. **19-23-1** to **19-23-4** illustrate a yoke to frame rotation indicator according to another embodiment of the present invention;

FIG. **20-1** is a perspective view of a short tube according to an embodiment of the present invention;

FIGS. **20-2** to **20-4** are various views illustrating attachment of the short tube to a swivel according to an embodiment of the present invention;

FIGS. **20-5-1** to **20-5-6** illustrate a short tube with elbow and swivel according to another embodiment of the present invention;

FIGS. **21-1** and **21-2** illustrate Velcro tabs for a headgear strap according to embodiments of the present invention;

FIGS. **22-1-1** to **22-1-8** are various views of a frame according to an embodiment of the present invention;

FIGS. **22-1-9** and **22-1-10** illustrate rotation of the yoke relative to the frame according to an embodiment of the present invention;

FIGS. **22-2** and **22-3** illustrate assembly of headgear yoke to a frame according to an embodiment of the present invention;

FIGS. **22-4** to **22-6** and **22-7-1** to **22-7-8** are various views of a headgear yoke according to an embodiment of the present invention;

FIGS. **22-8** to **22-13** are various views illustrate attachment of headgear yoke to a frame according to an embodiment of the present invention;

FIGS. **22-14** and **22-15** illustrate a ratchet arrangement between headgear yoke and frame according to an embodiment of the present invention;

FIG. **22-16** illustrates a fully assembled frame and headgear yoke according to an embodiment of the present invention;

FIGS. **22-16-1** and **22-16-2** illustrate an interference fit between the yoke and the frame according to an embodiment of the present invention;

FIGS. **22-17-1** to **22-17-2** illustrate relative movement between the frame and headgear yoke according to an embodiment of the present invention;

FIGS. **22-18-1** to **22-18-3** illustrate a mold for molding a frame according to an embodiment of the present invention;

FIGS. **22-19-1** to **22-19-7** illustrate headgear yoke attached to a headgear strap according to an embodiment of the present invention;

FIGS. **22-20-1** to **22-20-5** illustrate a fully assembled patient interface according to an embodiment of the present invention;

FIGS. **22-20-6** and **22-20-7** illustrate a back strap for a patient interface according to an embodiment of the present invention;

FIGS. **22-21-1** to **22-21-8** illustrate a left-hand-side (LHS) side strap with headgear yoke according to an embodiment of the present invention;

FIGS. **22-22-1** to **22-22-8** illustrate a right-hand-side (RHS) side strap with headgear yoke according to an embodiment of the present invention;

FIGS. **22-22-9** and **22-22-10** illustrate under-side and top-side views of a tab of hook material according to an embodiment of the present invention;

FIGS. **22-23-1** to **22-23-7** illustrate a fully assembled patient interface according to an embodiment of the present invention;

FIG. **22-24** is a perspective view showing a yoke engaged with a frame via a ball and socket joint according to an embodiment of the present invention;

FIG. **22-25** is a cross-sectional view showing the ball and socket joint of FIG. **22-24**;

FIG. **23** illustrates the difference in compression before bottoming out between prior art nasal pillow mask systems (Puritan-Bennett Breeze), related art nasal pillow system (ResMed Swift II) and an embodiment of the present invention;

FIG. **24** illustrates the difference in lateral movement that can be obtained in accordance with an embodiment of the present invention when compared to ResMed Swift nasal pillows;

FIG. **25***a* to FIG. **25***g* show cross-sectional profiles of a range of prior and related nasal pillow systems, as well as an embodiment of the present invention;

FIG. **26** shows a table comparing relative properties of the ResMed SWIFT mask and an embodiment of the present invention;

FIG. **27***a* to FIG. **27***l* show a range of views of a nasal pillow and gusset assembly in accordance with another embodiment of the present invention, FIG. **27** is similar to FIG. **16**;

FIG. **28** is a sketch illustrating how the nasal pillows and gusset align with the face in use;

FIG. **29** is a sketch comparing a nasal pillow of an embodiment of the present invention and a prior art nasal pillow when subject to a compression force;

FIG. **30** is a cross-section of headgear material according to an embodiment of the present invention;

FIGS. **31-1** and **31-2** are perspective views of a mask system according to another embodiment of the present invention;

FIGS. **32-1** and **32-2** are perspective views of a mask system according to another embodiment of the present invention;

FIGS. **33-1** and **33-2** are side and front views of a mask system according to another embodiment of the present invention;

FIG. **34** is a perspective view of a mask system according to another embodiment of the present invention;

FIG. **35** is an exploded view of a mask system according to another embodiment of the present invention;

FIG. **36** is a perspective view of a mask system according to another embodiment of the present invention;

FIG. **37** is a perspective view of a mask system according to another embodiment of the present invention;

FIG. **38** is a perspective view of a mask system according to another embodiment of the present invention;

FIGS. **39-1** and **39-2** are perspective views of a mask system according to another embodiment of the present invention;

FIG. **40** is a cross-sectional view of a mask system according to another embodiment of the present invention;

FIG. **41-1** illustrates a nasal prong assembly having a width and FIG. **41-2** illustrates a nasal prong assembly having a smaller width according to an embodiment of the present invention;

FIG. **41-3** is a cross-sectional view of the nasal prong assembly shown in FIG. **41-2**;

FIG. **42** is a cross-sectional view of a mask system according to another embodiment of the present invention;

FIG. **43** is a cross-sectional view of a mask system according to another embodiment of the present invention;

FIG. **44** is a cross-sectional view of a mask system according to another embodiment of the present invention; and

FIG. **45-1** illustrates a nasal prong assembly having a central axis and FIG. **45-2** illustrates a nasal prong assembly having a shifted central axis according to an embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

In broad terms, a patient interface in accordance with an embodiment of the invention may comprise three functional aspects: (i) interfacing, (ii) a positioning and stabilizing, and (iii) air delivery. These three functional aspects may be constructed from one or more structural components, with a given structural component potentially fulfilling more than one function. For example, a mask frame may serve as part of a positioning and stabilizing function and allow the supply of air.

In addition, a patient interface in accordance with an embodiment of the invention may perform other functions including venting of exhaled gases, decoupling of potentially seal disruptive forces and adjustment for different sized faces. Venting may be performed by different structures, such as a frame, an elbow and/or a conduit.

The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

In this specification, the word "comprising" is to be understood in its "open" sense, that is, in the sense of "including", and thus not limited to its "closed" sense, that is the sense of "consisting only of". A corresponding meaning is to be attributed to the corresponding words "comprise", "comprised" and "comprises" where they appear.

The term "air" will be taken to include breathable gases, for example air with supplemental oxygen. It is also acknowledged that the positive airway pressure (PAP) devices or flow generators described herein may be designed to pump fluids other than air.

Each illustrated embodiment includes features that may be used with the embodiments and/or components described in U.S. Patent Application Publication Nos. 2004-0226566, 2006-0137690, and 2005-0241644, PCT Application Publication Nos. WO 2005/063328, WO 2006/130903, and WO 2007/053878, and U.S. Provisional Application Nos. 60/835,442, filed Aug. 4, 2006, and 60/852,649, filed Oct. 19, 2006, as would be apparent to those of ordinary skill in the art. Each of the above noted applications are incorporated herein by reference in its entirety. However, it should be appreciated that any single feature or combination of features in any of the embodiments may be applied to other suitable mask arrangements, e.g., full-face, etc.

1 Interfacing

1.1 Introduction

In one form of the invention, the interfacing function is provided by a pair of nasal prongs (or "nasal pillows") that are placed at an entrance to the patient's nares. Each prong is structured to form an adequate seal with its respective naris and is shaped, oriented, sized and constructed so as provide a fit with a range of differently shaped and located nares.

As shown in FIGS. **2-1** to **2-2**, the nasal prong assembly **20** includes a base **22** and a pair of nasal prongs **24** provided to the base **22**. Each nasal prong **24** includes a generally conical, "volcano", or mushroom-shaped head portion **25** adapted to seal and/or sealingly communicate with a respective patient nasal passage (e.g., concave and oval prong designed to fit into the patients nares and seal against the rim of the nares) and a column or stalk **27** that interconnects the head portion **25** with the base **22**. The nasal prong assembly

20 is structured to be removably and replaceably attached to a substantially rigid frame **30** and be retained to the frame **30** by a clip **23** (such as that described in WO 2007/053878, which is incorporated herein by reference in its entirety). One or more vent openings **32** may be provided in the frame and/or base for CO_2 washout.

The nasal prong assembly **20** may be integrally formed in one-piece, e.g., by silicone in an injection molding process (e.g., LSR (liquid silicone rubber) and CMSR (compression molded silicon rubber) molding technology). However, the nasal prong assembly **20** may be formed in other suitable processes.

In an embodiment, one end of the nasal prong assembly is provided with a plug and the other end is provided with an elbow (e.g., swivel elbow). The positions of the elbow and the plug may be interchanged, according to preference, e.g., the typical sleeping position of the patient. In an alternative embodiment, both ends of the nasal prong assembly may be provided with an elbow. An air delivery tube is joined to the elbow or elbows to deliver a source of pressurized gas (e.g., 2-30 cmH2O).

In an embodiment, the nasal prong assembly may include a "low flow" version with a different pressure flow requirement.

The nasal prong assembly provides a lightweight, unobtrusive arrangement for delivering positive airway pressure as a means of therapy, e.g., for OSA.

The following discussion in the "Interfacing" section of this detailed description principally relates to the cone-shaped portion of the prong, other aspects of the prong—such as the stalk—will be discussed in more detail in subsequent sections.

1.2 Shape, Geometry and Anthropometrical Features

The nasal prongs may include geometry and/or anthropometrical features similar to the nasal prongs described in U.S. Patent Application Publication Nos. 2004-0226566, 2006-0137690 and PCT Application Publication Nos. WO 2006/130903, and WO 2007/053878, each of which is incorporated herein by reference in its entirety.

Also, rotating the nasal prong assembly in relation to the headgear can physically rotate the prongs in an anterior/posterior direction in relation to the nose. This flexibility effectively sets the prongs into an "exact" comfortable position for an individual user.

Further, the prong's stalk provides a flexible point to allow prong alignment and seal maintenance.

1.3 Orientation

For example, the orientation of the nasal prongs is designed to present the exit holes and the conical sealing surfaces as square to the nostril openings as possible. This increases the effectiveness of the seal. The prongs have been angled and rotated in relation to the base in order to provide this orientation for average anthropometry.

As shown in top view FIG. **2-3** (nostril angle), the rotation angle α of the prong **24** with respect to centerline CL may about 20-35 degrees, e.g., 27 degrees. As shown in front view FIG. **2-4** (alar angle), the inward rotation angle β of the prong **24** with respect to centerline CL may be about 15-20 degrees, e.g., 17 degrees. However, other suitable angles are possible.

1.4 Sizing

In combination with this orienting geometry, the prongs can be adapted to nasal geometry variations from patient to patient in a number of ways. Firstly, the prongs may be available in multiple sizes (e.g., extra small, small, medium, large, extra large). The variant geometry between sizes may be the diameters of the oval prong profile.

1.5 Spacing

Spacing of the pillows is illustrated in FIG. **16-8** described below.

1.6 Construction

1.6.1 Dual-Wall Nasal Prongs

In an embodiment, the nasal prongs **24** may be similar to nasal prongs those described in WO 2006/130903, which is incorporated herein by reference in its entirety.

For example, as shown in FIG. **3-1**, the head portion **25** of each nasal prong **24** may include a dual or double-wall arrangement including an inner wall **26** (inner membrane or support membrane) and an outer wall **28** (outer membrane or sealing membrane) that surrounds the inner wall **26**. The outer wall **28** may be relatively thin (e.g., 0.35 mm) to conform to the shape of the patient's nose and provide a more compliant seal. In addition, the thin outer wall effectively finds its own seal with very little tweaking, which reduces the time for set-up. In an embodiment, the dual-wall prongs **24** may be manufactured in a manner as described in WO 2006/130903, e.g., fold or invert one wall with respect to the other wall.

One of the advantages of dual wall nasal prongs that may be used to improve jetting performance is that it is possible to reorient the inner exit hole at any angle while retaining a "square" sealing orientation for the outer wall.

One aspect of dual pillows construction is that the inner surface of the outer membrane may be frosted to facilitate removal from the molding tool. Also, the outer surface of the outer membrane may be frosted, e.g., for comfort and for improving fitting to nose because less sticking.

1.6.2 Alternative Nasal Prong Embodiments

The following embodiments describe alternative prong arrangements that are structured to improve sealing comfort and/or fitting. In embodiments, the prong arrangements may be structured to reduce and/or eliminate the air jetting effect, e.g., redirect air flow direction (e.g., away from sensitive regions such as the septum), diffuse air flow or create turbulence, and/or change the prong orifice in order to reduce and/or eliminate air jetting effects. Reducing and/or eliminating the air jetting effect may provide increased comfort across a wider pressure range and/or reduced concentrated dryness and cold burning sensation. In addition, adding turbulence may reduce noise.

Additional prong arrangements to improve comfort and fitting are described in U.S. Provisional Application Nos. 60/835,442, filed Aug. 4, 2006, and 60/852,649, filed Oct. 19, 2006, each of which is incorporated herein by reference in its entirety.

The nasal prong embodiments described below include a dual or double-wall head portion. While embodiments described below relate to dual-wall nasal prongs, it should be appreciated that embodiments of the invention may be adapted for use with single-wall nasal prongs and/or multi-wall nasal prongs (e.g., 2 or more walls).

Dual Wall with Hood

FIG. **5-1** illustrates a nasal prong **224** according to another embodiment of the present invention. In the illustrated embodiment, the inner wall **226** includes a hood **234** (e.g., integrally formed with the inner wall) adapted to reorient the exit hole and change the air flow direction to reduce and/or eliminate the air jetting effect, e.g., direct flow away from the septum.

As illustrated, the hood **234** is provided to anterior and medial portions (i.e., front and middle portions) of the inner wall **226** along the perimeter of the orifice. The hood **234** is structured to direct the air posteriorly, e.g., towards the rear, rather than straight up the nasal passage. In addition, the hood **234** is structured to direct the air laterally, e.g., towards the side, rather than towards the septum. Thus, the hood **234** is structured to change the air flow in two planes such that the hood **234** directs the air flow away from the septum and avoids direct contact with sensitive areas of the anterior nose.

Dual Wall with Dome

FIG. **5-2** illustrates a nasal prong **324** according to another embodiment of the present invention. In the illustrated embodiment, the inner wall **326** includes a dome **335** (e.g., integrally formed with the inner wall) adapted to change the air flow direction to reduce and/or eliminate the air jetting effect, e.g., direct flow away from the septum. The dome **335** may also reduce pressure drop and/or impedance.

As illustrated, the dome **335** has a hemispherical shape that extends over the orifice of the inner wall **326** and provides an eccentrically placed exit hole to direct the air away from sensitive regions of the patient's nose, e.g., septum. In an embodiment, the exit hole may be positioned to direct air similar to the hood described above, e.g., direct the air posteriorly and laterally.

Dual Wall with Blocked Orifice and Holes on Inner and Outer Walls

FIG. **5-3** illustrates a nasal prong **424** according to another embodiment of the present invention. In the illustrated embodiment, the orifice of the inner wall **426** is blocked and the inner wall **426** includes one or more holes **436**. As illustrated, the holes **436** are provided to a posterior side of the inner wall **426**. However, the holes **436** may be provided along any suitable portion of the inner wall **426**. Also, each hole **436** has a generally circular or oval shape. In alternative embodiments, each hole **436** may have any other suitable shapes, e.g., non-circular such as elongated slots or square or rectangular openings. In addition, the inner wall **426** may have any suitable number of holes **436**, e.g., 1, 2, 3, or more holes.

Further, the outer wall **428** may optionally include one or more holes **437**. In the illustrated embodiment, the holes **437** are provided to an upper region of the outer wall (e.g., near the orifice) on a medial portion of the outer wall which is oriented towards the patient's face in use (e.g., near the patient's top lip). Similar to the holes **436** in the inner wall, the holes **437** in the outer wall may be provided to other suitable portions of the outer wall, may be have other suitable shapes, and may have any suitable number of holes, e.g., 1, 2, 3, or more holes.

In the illustrated embodiment, the holes **436** in the inner wall are larger than the holes **437** in the outer wall. However, other suitable sizes are possible.

In use, the holes **436**, **437** disperse air as it passes through the prong **424**, e.g., to create turbulence and/or reduce impedance.

Dual Wall with Blocked Orifice and Castellated Openings

FIG. **5-4** illustrates a nasal prong **524** according to another embodiment of the present invention. In the illustrated embodiment, the orifice of the inner wall **526** is blocked and the inner wall **526** includes one or more openings **536** around the perimeter or rim of the inner wall **526** adjacent the blocked orifice. As illustrated, the openings **536** each include a generally square or rectangular shape to provide a castellated-type arrangement at the top of the inner wall **526**. However, the openings **526** may have other suitable shapes and may be provided in any suitable number, e.g., 5, 6, 7, or more openings.

In use, the openings **536** direct the flow laterally from the blocked orifice to disperse and/or diffuse air as it passes through the prong, e.g., to create turbulence.

In an alternative embodiment, the orifice of the inner wall **526** may not be blocked and the top of the inner wall **526** may include the castellated-type arrangement to disperse air.

Dual Wall with Elongated Inner Wall

FIG. **5-5** illustrates a nasal prong **624** according to another embodiment of the present invention. In the illustrated embodiment, the inner wall **626** is elongated or extended so that the orifice of the inner wall **626** is substantially higher than the orifice of the outer wall **628**. In addition, the inner wall **626** has a tube-like configuration with the orifice of the inner wall **626** oriented to change the air flow direction to reduce and/or eliminate the air jetting effect, e.g., direct flow away from the septum. In an embodiment, the orifice may be oriented to direct air similar to the hood described above, e.g., direct the air posteriorly and laterally. For example, the inner wall **626** extends further inside the patient's nostril to direct flow away from the inner septum.

Dual Wall with Insert

FIG. **5-6** illustrates a nasal prong **724** according to another embodiment of the present invention. In the illustrated embodiment, an insert **738** (i.e., formed separately from the prong) is provided to the inner wall **726** that is adapted to change the air flow direction to reduce and/or eliminate the air jetting effect, e.g., direct flow away from the septum.

As illustrated, the insert **738** includes a base **738(1)** adapted to support the insert **738** in a operative position adjacent the orifice of the inner wall **726** and a head **738(2)** that provides an exit opening to change the air flow direction. The length of the head **738(2)** may be changed, e.g., customized length for particular patient, to provide a longer or shorter exit from the inner wall **726**. In the illustrated embodiment, the wall of the insert **738** may be constructed of a foam or silicone material. Alternatively, the entire volume of the insert **738** may be constructed of foam, e.g., similar to the foam insert described below.

The insert **738** is secured to the inner wall **726** to prevent removal and possible inhalation in use. In an embodiment, the inner wall **726** may include an annular flange or shoulder around the orifice adapted to support or secure the insert **738** in position. However, the insert **738** may be supported in its operative position in other suitable manners, e.g., adhesive, friction fit, mechanical interlock, etc. In an embodiment, a connector may be provided between inserts of adjacent prongs to prevent discharge of an insert through the orifice, e.g., during inspiration.

In an embodiment, the insert **738** may be retrofitted to an existing nasal prong in order to direct flow in a similar manner to a hood. For example, the exit opening of the insert **738** may be positioned to direct air in a similar manner to the hood described above, e.g., direct the air posteriorly and laterally. Thus, the insert **738** may be made as a "spare part" or separate accessory and used only when the patient is suffering from jetting effect with an existing nasal prong assembly.

Dual Wall with Internal Ledge

FIG. **5-7-1** illustrates a nasal prong **824** according to another embodiment of the present invention. In the illustrated embodiment, the prong **824** includes an internal ledge or shelf **839** that extends inwardly from the inner wall **826** to block at least a portion of the flow exiting the orifice of the inner wall **826**. In an embodiment, the ledge or shelf **839** is positioned on a medial portion of the inner wall **826** so that the ledge or shelf **839** is adapted to block flow nearest to the patient's septum in use. However, the ledge or shelf **839** may be provided at other portions of the inner wall **826** to block air flow directed at sensitive regions.

As illustrated, the ledge or shelf **839** extends inwardly from the edge of the orifice. In an alternative embodiment, the ledge or shelf **839** may be spaced downwardly from the edge of the orifice, e.g., to reduce impedance.

In yet another alternative, as shown in FIG. **5-7-2**, a ledge or shelf **839** may be provided to a single wall prong. For example, the ledge or shelf **839** may extend inwardly from the wall of the prong to block at least a portion of the flow exiting the orifice, e.g., block flow nearest to the patient's septum.

Dual Wall with Mesh or Gauze

FIG. **5-8** illustrates a nasal prong **924** according to another embodiment of the present invention. In the illustrated embodiment, the prong **924** includes mesh or gauze **940** constructed of a suitable mesh or gauze material (e.g., auxetic materials possible) to diffuse the flow of air. As illustrated, the mesh or gauze **940** is provided at the base of the head portion. However, the mesh or gauze **940** may be provided at other suitable locations along the prong, e.g., at the base of the stalk. In an embodiment, the mesh or gauze **940** may be provided as an insert that is retrofit to an existing nasal prong.

In use, the mesh or gauze **940** increases the dispersion and turbulence of the air as it exits the prong orifice and enters the patient's nasal passage.

In an alternative embodiment, the mesh or gauze **940** may be designed as an anti-asphyxia valve (AAV) style flap adapted to cover the prong orifice on inspiration and fall open on expiration to reduce impedance.

Dual Wall with Exit Gate

FIG. **5-9-1** illustrates a nasal prong **1024** according to another embodiment of the present invention. In the illustrated embodiment, the prong **1024** includes a pinwheel-shaped or star-shaped gate **1041**, e.g., integrally formed with the prong, provided at the rim or exit orifice of the inner wall **1026**. As illustrated, the pinwheel-shaped or star-shaped gate **1041** includes a hub **1041**(**1**) and a plurality of vanes or legs **1041**(**2**) extending radially from the hub **1041**(**1**). Each vane **1041**(**2**) tapers from the rim to the hub.

In use, the gate **1041** increases the dispersion and turbulence of the air as it exits the orifice and enters the patient's nasal passage.

It should be appreciated that the gate **1041** may be provided at other suitable locations along the prong (e.g., at the outer wall, along the stalk, etc.), and the gate **1041** may have other suitable shapes and orientations. In addition, the gate **1041** may have any suitable number of vanes **1041**(**2**), e.g., 3, 4, 5, or more vanes.

For example, FIG. **5-9-2** illustrates a prong **1124** with a gate **1141** according to another embodiment of the present invention. As illustrated, the gate **1141** includes a hub **1141**(**1**) and a plurality of vanes **1141**(**2**) extending radially from the hub **1141**(**1**). Each vane **1141**(**2**) is helical or in the shape of a propeller blade to disperse the air and create turbulence as it exits the orifice.

In yet another alternative, such a pinwheel-shaped or star-shaped gate may be provided to a single wall prong, e.g., at the exit orifice of the prong.

Dual Wall with Foam Insert

FIG. **5-10** illustrates a nasal prong **1224** according to another embodiment of the present invention. In the illustrated embodiment, the prong **1224** includes a foam insert **1238** constructed of a foam material, e.g., low density foam material, to diffuse the flow of air. As illustrated, the foam insert **1238** is provided within the cavity defined by the inner wall **1226**. However, the foam insert **1238** may be provided at other suitable locations along the prong, e.g., within the stalk. In an embodiment, the foam insert **1238** may be provided as a "spare part" that is adapted to be retrofitted to an existing nasal prong.

The foam insert **1238** may be supported by the inner wall **1226** in its operative position in any suitable manner, e.g., adhesive, friction fit, mechanical interlock, etc. For example, the foam insert **1238** may be squeezed into the cavity and then allowed to resiliently expand into engagement with the inner wall **1226**. In an embodiment, a connector may be provided between foam inserts of adjacent prongs to prevent discharge of an insert through the orifice, e.g., during inspiration.

In use, air passes through the thickness of the foam insert **1238** which increases the dispersion and turbulence of the air as it exits the prong orifice and enters the patient's nasal passage.

In another alternative embodiment, each prong may include an insert constructed of a silicone material and provided with relatively small channels through the interior to diffuse the flow of air in use. Inserts constructed of other suitable materials are also possible, e.g., Gore-Tex.

In yet another embodiment, the insert (e.g., foam or silicone insert) may provide a mechanical valve type arrangement. For example, the insert may be adapted to cover the orifice and act as a diffuser on inspiration, and open or uncover the orifice on expiration. In an embodiment, the insert may include a cone-shape with a hollow center to facilitate movement between covering and uncovering positions.

Dual Wall with Cut Inner Wall

FIG. **5-11** illustrates a nasal prong **1324** according to another embodiment of the present invention. In the illustrated embodiment, the orifice of the inner wall **1326** and/or the orifice of the outer wall **1328** is cut at an angle, e.g., 45° angle, to direct air flow. The angled orifice(s) changes the air flow direction to reduce and/or eliminate the air jetting effect, e.g., direct flow away from the septum. In addition, the angled orifice(s) increase the size of the orifice(s) (e.g., with respect to a non-cut or non-angled orifice) to provide lower impedance. The prong orifice(s) may be cut at any suitable angle, e.g., angle may be dependent on the shape of the patient's nostrils.

Dual Wall with Chevron-Pattern Exit Hole

FIGS. **5-12-1** and **5-12-2** illustrate nasal prongs **1424** according to another embodiment of the present invention. In the illustrated embodiment, the orifice of the inner wall **1426** and/or the orifice of the outer wall **1428** includes a chevron-pattern or toothed arrangement around its perimeter. In FIG. **5-12-1**, the prong includes a chevron-pattern around the orifice of the inner wall, **1426**. In FIG. **5-12-2**, the prong includes a chevron-pattern around the orifice of the inner and outer walls **1426**, **1428**.

However, the orifice may have other suitable shapes or patterns around its perimeter. For example, FIGS. **5-12-3** and **5-12-4** are tope top views of prongs including orifices with a series of contours or lobes **1442**, e.g., 3, 4, 5, 6, or more contours or lobes.

In use, the non-oval-shaped orifice increases the dispersion and turbulence of the air as it exits the orifice and enters the patient's nasal passage.

Dual Wall with Alternative Base

FIGS. **5-13-1** and **5-13-2** illustrate a nasal prong **1524** and base **1522** according to alternative embodiments of the present invention. In the illustrated embodiment, the base **1522** that supports the prong **1524** may include different thicknesses to vary a trampoline or bounce effect provided by the base **1522**. For example, FIG. **5-13-1** illustrates a base

1522 wherein d**1** is about 0.6 mm and d**2** is about 0.75-0.85 mm, and FIG. **5-13-2** illustrates a base **1522** wherein d**1** is about 0.85 mm and d**2** is about 0.75 mm. In each embodiment, the stalk **1527** may have a length d**3** of about 5.2 mm and a thickness d**4** of about 0.6-1.0 mm. Also, in each embodiment, the outer wall **1528** may have a thickness d**5** of about 0.1 to 0.5 mm, or about 0.35±0.1 mm, or about 0.3±0.1 mm, or about 0.45 mm. The relatively thin outer wall **1528** may be more comfortable and compliant. The inner wall **1526** may have a thickness d**6** of about 0.4 to 1.0 mm.

It is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. Also, such base may be provided to a nasal prong having a single wall configuration.

Manufacturing

In an embodiment, the dual-wall prong may be molded into its operative dual wall construction. In an alternative embodiment, one of the inner and outer walls may be molded in an open position and then inverted or folded to form the dual wall construction.

In yet another embodiment, as shown in FIG. **5-13-3**, a prong **4424** may include a multi-wall construction (e.g., triple-wall construction) in which two or more walls **4426(1)**, **4426(2)** are molded in an open position and then inverted or folded with respect to another wall **4426(3)** to form the multi wall construction (e.g., three wall concentric arrangement). Exemplary folded wall arrangements are described in WO 2006/130903, which is incorporated herein by reference in its entirety.

Thin Wall Thickness

FIG. **5-14-1** illustrates a nasal prong **1624** according to another embodiment of the present invention. In the illustrated embodiment, the outermost wall **1628** (e.g., the outer wall of a multi-wall prong or the single wall of a single wall prong has a relatively thin wall thickness (e.g., thickness less than about 0.45 mm (e.g., 0.35 mm)) so that the outermost wall is adapted to bulge outwardly or slightly inflate (as indicated in dashed lines in FIG. **5-14-1**) in use to accommodate and/or conform to the patient's nose in use.

For example, FIG. **5-14-2** is a plan view of the outermost wall **1628** to illustrate its generally oval or elliptical shape, and FIGS. **5-14-3** and **5-14-4** are cross-sectional views through minor and major axes of the outermost wall respectively. As illustrated, the sides of the wall are structured to bulge more outwardly than the ends of the wall in use. Specifically, the sides of the wall are adapted to move from a generally concave shape to a generally convex shape in use (see FIG. **5-14-3**), and the ends are adapted to move from a generally concave shape to a generally straight or linear shape in use (see FIG. **5-14-4**). Such arrangement facilitates sealing and compliance of the prong with the patient's nose in use as the thin wall is able to conform to the patient's nasal contours.

Support of Thin Outer Wall

A support structure may be provided to a thin outer wall (such as that described above in FIGS. **5-14-1** to **5-14-4**) to add rigidity and/or facilitate alignment and engagement of the thin outer wall with the patient's nose before use. In addition, the support structure may be constructed and arranged to create turbulence in use.

For example, as shown in FIGS. **5-15-1** and **5-15-2**, the thin outer wall **1728** may include one or more ribs **1743** that extend along an interior surface of the outer wall, e.g., integrally formed with the thin outer wall.

In another embodiment, as shown in FIG. **5-16**, the thin outer wall **1828** may include a plurality of ribs **1843** that form concentric ribs or rings along an interior surface of the outer wall **1828**, e.g., integrally formed with the outer wall. The ribs **1843** may extend around the entire interior perimeter of the outer wall and/or the ribs **1843** may extend around portions of the interior perimeter of the outer wall.

In another embodiment, as shown in FIG. **5-17**, the outer wall **1928** may include a thin region **1928(1)** positioned between a thicker rim **1928(2)** along the orifice and a thicker base **1928(3)**.

In another embodiment, as shown in FIG. **5-18**, the outer wall **2028** may include a plurality of notches **2044** that form thinned sections **2028(1)** along the outer wall **2028**. The thinned sections **2028(1)** may extend around the entire interior perimeter of the outer wall and/or the thinned sections **2028(1)** may extend around portions of the interior perimeter of the outer wall.

In another embodiment, a dual wall prong may be provided and the inner wall may be substantially rigid (e.g., thickness greater than about 0.4 mm (e.g., 0.4 to 0.8 mm)) in order to support and guide the thin outer wall into engagement with the patient's nose before use. That is, the thin outer wall provides a seal-forming thinner wall and the inner wall provides a structure-defining thicker wall that adds stiffness to the thin outer wall as it is engaged and aligned with the patient's nose before use. In use, pressurized air causes the outer wall to bulge outwardly into conformance with the patient's nose, e.g., pressure supported seal.

In another embodiment, as shown in FIGS. **5-19-1** to **5-19-3**, a support rod **2145** may be operatively engaged with the outer wall **2128** of the prong in order to support and guide the outer wall **2128** thereof into engagement with the patient's nose before use. As shown in FIG. **5-19-3**, each prong includes a pinwheel-shaped or star-shaped gate **2141** provided at the rim of the outer wall **2128**. The support rod **2145** includes a first end **2145(1)** engaged with the hub of the gate **2141** and a second end **2145(2)** that extends through the base **2122** supporting the prongs. In use, the patient can slidably move the support rod **2145** via the exposed first end **2145(2)** in order to hold the outer wall in a sufficiently taut or extended position for engagement with the patient's nose before use (see FIG. **5-19-2**).

In another embodiment, as shown in FIGS. **5-20-1** to **5-20-2**, support projections **2246** may be provided to the base **2222** supporting the prongs that is adapted to operatively engage with the outer wall **2228** of a respective prong in order to support and guide the outer wall thereof into engagement with the patient's nose before use. As illustrated, each support projection **2246** is provided to the lower wall of the base **2222** in alignment with a respective prong and includes a generally cone-like shape. In use, the patient can deflect or deform the base **2222** so that each support projection **2246** moves from an initial position (FIG. **5-20-1**) into an engaged position (FIG. **5-20-2**) with the outer wall **2228** of a respective prong. In the engaged position of FIG. **5-20-2**, the support projection **2246** supports or holds the outer wall **2228** in a sufficiently taut or extended position for engagement with the patient's nose before use.

1.6.3 Ball-Type Insert

FIG. **5-21** illustrates a nasal prong assembly **2320** according to another embodiment of the present invention. In the illustrated embodiment, a ball-type insert **2338** (e.g., silicone or plastic ball) is provided to the interior of each prong **2324**. The ball-type insert **2338** has a diameter that is sufficiently larger than the diameter of the prong orifice to prevent discharge of the ball-type insert **2338** through the orifice, e.g., during inspiration. In use, the ball-type insert **2338** moves or rotates freely within the prong interior to introduce variable direction air flow, e.g., random diffuse of air, to reduce and/or eliminate the air jetting effect, e.g., reduce air flow time with specific areas of the patient's nose (e.g., septum).

In an embodiment, the ball-type insert **2338** may have a sphere-like shape and may include one or more perforations, grooves, dimples, or detents along its exterior surface. However, the ball-type insert **2338** may have other suitable shapes, e.g., non sphere-like.

In an embodiment, a connector **2338(1)** may be provided between ball-type inserts **2338** of adjacent prongs to prevent discharge of the inserts **2338** through respective orifices.

It should be appreciated that the ball-type insert **2338** may be adapted for use with dual-wall nasal prongs.

1.6.4 One-way Valve

In another embodiment, a one-way valve may be provided to the vent arrangement of the nasal prong assembly to reduce the pressure of exhalation and allow easier nose breathing. The one-way valve is adapted to pivot or otherwise move between (1) an open position that uncovers the vent arrangement to allow venting during exhalation, and (2) a closed position that covers at least a portion of the vent arrangement during inhalation. The valve may provide variable vent flow in the closed position, e.g., depending on closed portion of vent arrangement. The threshold pressure may be set at therapy pressure, such that the valve moves to the open position during exhalation as added pressure from the patient's lungs exceeds therapy pressure.

1.6.5 Blocking Flap

FIGS. **5-22-1** and **5-22-2** illustrate a nasal prong assembly **2420** according to another embodiment of the present invention. As illustrated, the nasal prong assembly **2420** includes a base **2422** and a pair of nasal prongs **2424** provided to the base.

In the illustrated embodiment, a blocking flap or valve **2447** may be provided to one or both ends of the base **2422** (e.g., depending on whether air enters the base via one or both ends) to control the flow of air entering the base **2422** and hence the pair of nasal prongs **2424**. As illustrated, the blocking flap or valve **2447** is adapted to pivot or otherwise move between (1) an open or partially open position that uncovers at least a portion of the end of the base to allow pressurized air to enter the base during inhalation (see FIG. **5-22-1**), and (2) a closed position that blocks or covers the end of the base to prevent pressurized air from entering the base during exhalation and venting (see FIG. **5-22-2**). This arrangement is adapted to block incoming flow from the PAP device on exhalation to reduce the pressure of exhalation and allow easier nose breathing.

In an alternative embodiment, a vibratable flap may be provided along the flow path to introduce random diffuse of air.

1.6.6 Change Frequency

In another embodiment, the prong may be configured to change frequency, e.g., like jet engine.

1.6.7 Common Stalk

FIGS. **5-23-1** and **5-23-2** illustrate a nasal prong assembly **2520** according to alternative embodiments of the present invention. As illustrated, each nasal prong assembly **2520** includes a base **2522**, a pair of nasal prongs **2524**, and a common support or stalk **2523** that interconnects the prongs **2524** with the base **2522**.

In FIG. **5-23-1**, each prong **2524** includes a relatively short stalk **2527** provided to the common stalk **2523**. In use, the common stalk **2523** and/or the relatively short stalk **2527** may provide a trampoline or bounce effect.

In an alternative embodiment, as shown in FIG. **5-23-2**, the relatively short stalk may be eliminated and each prong **2524** may be directly coupled to the common stalk **2523**. In such embodiment, the common stalk **2523** may provide a trampoline or bounce effect.

1.6.8 Nasal Insert

FIGS. **5-24-1** and **5-24-2** illustrate nasal inserts **2624** according to alternative embodiments of the present invention. In use, the nasal insert **2624** is inserted into the patient's nasal passage and retained therein by inflation of the outer wall **2628**.

As illustrated, the nasal insert **2624** includes a dual or double-wall arrangement with an inner wall **2626** and an outer wall **2628** that surrounds the inner wall **2626**. An air pocket **2648** is provided between the inner and outer walls **2626**, **2628**. In use, air enters the pocket **2648** to inflate the outer wall **2628** or cause the outer wall **2628** to bulge more outwardly. Such arrangement allows the outer wall **2628** to seal and conform within the patient's nasal passage.

As shown in FIG. **5-24-1**, the insert **2624** may provide an open ended pocket wherein air is adapted to enter the pocket **2648** via the opening between free ends of the inner and outer walls **2626**, **2628**.

Alternatively, as shown in FIG. **5-24-2**, the insert **2624** may provide a closed pocket wherein air is adapted to enter the pocket **2648** via one or more openings **2636** provided through an intermediate portion of the inner wall **2626**.

1.6.9 Alternative Embodiments

The following figures illustrate embodiments structured to improve seal, stability, and/or comfort, for example.

FIG. **5-25** illustrates a nasal prong **2724** according to another embodiment of the present invention. As illustrated, the nasal prong **2724** includes a dual or double-wall head portion. Specifically, the head portion includes an outer wall **2728** and an inner wall **2726** that is inverted internally or looped over at the top of the outer wall **2728** to form the dual wall construction. This arrangement provides a rounded top to strengthen the top which may facilitate insertion of the prong **2724** into engagement with the patient's nostril. That is, this arrangement provides one continuous wall that is engaged with the nostril, rather than two separate walls such as embodiments of the dual wall configurations described above. Such arrangement may also enhance the seal of the head portion and may reduce the time of mask set-up as the dual wall configuration provides more ability to seal.

FIG. **5-26** illustrates a dual wall nasal prong **2824** according to another embodiment of the present invention. As noted above, the outer wall may be relatively thin to enhance conformance to the patient's nasal contours. In the illustrated embodiment, the rim **2828(1)** of the outer wall **2828** may be thicker or more rigid to stiffen the top of the outer wall **2828**, e.g., to prevent creeping out of the outer wall as indicated in dashed lines. However, the outer wall **2828** may include other support structures or mechanisms to stiffen the outer wall and/or enhance the seal, e.g., ribs as described above.

FIG. **5-27** illustrates a dual wall nasal prong **2924** according to another embodiment of the present invention. In the illustrated embodiment, the outer wall **2928** loops over or rolls over the inner wall **2926**. That is, the outer wall **2928** provides a rolled edge **2928(1)** that rolls or curls inwardly and at least partially into the orifice of the inner wall **2926**. A gap is provided between the free ends of the inner and outer walls **2926**, **2928**. The rolled edge **2928(1)** may taper towards its free end. This arrangement provides a rounded top to strengthen the top to facilitate insertion in use, e.g., similar to the prong shown in FIG. **5-25**. Also, this arrangement holds the outer wall **2928** and prevents pulling side-to-side.

FIG. **5-28** illustrates a dual wall nasal prong **3024** according to another embodiment of the present invention. As illustrated, the outer wall **3028** is inverted externally or looped over at the top of the inner wall **3026** to form the dual wall construction. This arrangement provides a rounded top to strengthen the top to facilitate insertion in use, e.g., similar to the prong shown in FIG. **5-25**. In an alternative embodiment, the outer wall **3028** may be inverted internally. Pressurized air may help to maintain the form of the prong in use.

FIG. **5-29** illustrates a dual wall nasal prong **3124** according to another embodiment of the present invention. As illustrated, the outer wall **3128** is inverted externally or folded outwards over the outside of the inner wall **3126** to form the dual wall construction. This arrangement provides a rounded top or rolled over end to facilitate insertion in use. In the illustrated embodiment, the inner and outer walls **3126**, **3128** are bent and/or contoured along their length to provide flexibility in use. Pressurized air may help to pull the inner wall **3126** into the patient's nose in use.

FIG. **5-30** illustrates a nasal prong **3224** according to another embodiment of the present invention. As illustrated, the stalk **3227** of the nasal prong includes a gusset portion or flexing detail **3233** to add flexibility and articulation of the nasal prong in use. That is, the gusset portion **3233** may facilitate bending, stretching, and/or compressing of the nasal prong in use. Such arrangement may improve seal and stability of the prong in use. Pressurized air may expand the gusset portion **3233** so that it increases the projected surface area on the patient's nose, e.g., to improve seal.

FIG. **5-31** illustrates a nasal prong assembly **3320** according to another embodiment of the present invention. As illustrated, the stalk **3327** of each prong **3324** is sunken, recessed, or inset into the base **3322** to define a recess **3349** surrounding the stalk **3327**. Such arrangement increases the length/height of the prongs **3324** (e.g., add extra length to the stalks **3327**) without increasing the overall height of the prongs **3324** with respect to the base **3322**. In addition, the interface between each stalk **3327** and the base **3322** provides a trampoline or bounce effect. This arrangement allows greater extension, compression, and rotation of each prong to facilitate sealing in use. In addition, extension, compression, and rotation of the prongs (as indicated by the arrows in FIG. **5-31**) acts as a form of "suspension" so that the base **3322** can move away from the prongs without disrupting the seal. Further, the recessed suspension arrangement allows the patient's fingers to reach underneath the prongs **3324** in order to adjust them in the nose in use.

In an embodiment, the prongs may be molded in one piece with the base, and the recess surrounding each prong is exposed to the molding tool's open and shut direction, e.g., to avoid an undercut.

FIGS. **5-32-1** to **5-32-5** illustrate a nasal prong **3424** according to another embodiment of the present invention. As illustrated, the prong **3424** may be formed using an "over-the-center" molding technique wherein the prong **3424** is molded in an extended position (as shown in FIGS. **5-32-1** and **5-32-3**) with a detail or over-the-center feature **3439** (e.g., thin wall) that allows the prong **3424** to sink or be recessed into the base **3422** (as shown in FIGS. **5-32-2** and **5-32-4**). That is, the prong **3424** is structured to hold the position shown in FIGS. **5-32-2** and **5-32-4** when assembled, which is similar to the prongs shown in FIG. **5-31**. As noted above, such arrangement provides a long stalk length and trampoline base to allow greater articulation (e.g., extension, compression and rotation) of each prong in use (e.g., as shown by the rotated prong in FIG. **5-32-5**). Also, the recess surrounding each prong **3424** does not include an undercut.

FIG. **5-33** illustrates a dual wall nasal prong **3524** according to another embodiment of the present invention. As illustrated, the outer wall **3528** surrounds and loops over the inner wall **3526**. In the illustrated embodiment, both the inner and outer walls **3526**, **3528** provide a rolled edge **3526(1)**, **3528(1)** respectively that rolls or curls inwardly. The rolled edge **3526(1)**, **3528(1)** may taper towards its free end. This arrangement facilitates insertion into the patient's nostrils, and may provide a seal with the patient's nostrils that is similar to the seal provided by dual wall nasal or mouth cushions, e.g., see ResMed's Mirage® mask.

FIG. **5-34** illustrates a nasal prong **3624** according to another embodiment of the present invention. As illustrated, the nasal prong **3624** includes an compression and extension mechanism **3633** to improve flexibility and comfort of the nasal prong **3624** in use. In the illustrated embodiment, the compression and extension mechanism **3633** is provided to the stalk **3627** and includes a bellows or accordion-like configuration with multiple pleats that allow compression and extension of the prong in use. Such arrangement provides maximum extensions in a small area.

FIG. **5-35** illustrates a nasal prong **3724** according to another embodiment of the present invention. As illustrated, the nasal prong **3724** includes a recessed trampoline base **3631** such as that shown in FIG. **4-1** described below. In such embodiment, when the prong **3724** has been fully compressed, the patient's nose may be supported on nose support areas provided by the base **3722**, which provides extra stability in use. That is, when the prongs **3724** have been fully compressed, the prongs will travel with the patient's nose, e.g., if there is mask movement. As illustrated, each prong has an axis that is angled with respect to a centerline CL of the base.

FIG. **5-36-1** illustrates a nasal prong assembly **3820** according to another embodiment of the present invention. As illustrated, a support structure, e.g., silicone wings **3845**, may extend from the nasal prong assembly **3820** to stabilize or support the nasal prong assembly **3820** against the patient's cheek and/or chin.

In an embodiment, as shown in FIG. **5-36-2**, a headgear strap **3853** may be coupled to each wing **3845**, e.g., via cross-bar **3845(1)** or other headgear attachment point provided to the wing, so that tension of the headgear strap **3853** may press or force the wing **3845** into the patient's face. Moreover, the headgear load or tension is applied to the wing **3845** in order to take the load off the prongs, i.e., decouple headgear from the prongs. This arrangement facilitates adjustment and improves comfort in the patient's nostrils.

In an embodiment, headgear straps of headgear may be structured to utilize skeletal features of the patient's face to achieve stability (e.g., increase surface area of straps). For example, as shown in FIG. **5-37**, the side strap **3953** of headgear and/or a silicone pad provided to the side strap **3953** may be profiled or contoured to capture the cheek bone of the patient's face in use.

FIG. **5-38** illustrates a nasal prong assembly **4020** according to another embodiment of the present invention. As illustrated, a strap **4045** is provided to the nasal prongs **4024** to link the nasal prongs **4024** and facilitate adjustment of the nasal prongs **4024** in use. In the illustrated embodiment, the strap **4045** includes a linking member **4045(1)** that links the prongs **4024** so that the prongs are connected and support one another. Also, the strap **4045** includes a finger tab **4045(2)** that protrudes outwardly from one of the prongs **4024**. The free end of the finger tab **4045(2)** may include one or more gripping protrusions **4045(3)**. In use, the finger tab **4045(2)** may pulled and/or pushed to adjust the position of the prongs **4024** in the patient's nose.

In the illustrated embodiment, the strap **4045** extends along the base of the head portion of the prongs **4024**. However, the strap may engage the prongs at other suitable locations. In an embodiment, the strap **4045** may be integrally formed in one piece with the prongs **4024**. In an alternative embodiment, the strap **4045** be formed separately from the prongs (e.g., from a silicone material with sufficient rigidity to allow pulling/pushing) and attached or retrofit to the prongs **4024**. For example, the strap **4045** may include spaced openings for receiving respective prongs **4024** therethrough.

Also, the strap **4045** adds stability to the prongs **4024** by preventing tube drag from pulling prongs out of engagement with the patient's nose. That is, the linking member allows the prong that normally wants to draw out of the patient's nose due to tube drag to be held in place by the other prong.

FIG. **5-39** illustrates a nasal prong assembly **4120** according to another embodiment of the present invention. In the illustrated embodiment, a generally U-shaped inlet tube adaptor **4115** is provided (e.g., retrofit) to the nasal prong assembly **4120** to center the inlet tube **4114** and remove the asymmetric nature of the interface (e.g., inlet tube typically provided to only one side of the nasal prong assembly). As illustrated, the inlet tube adaptor **4115** includes side portions **4115(1)** adapted to connect to respective ends of the nasal prong assembly **4120** and an intermediate portion **4115(2)** adapted to connect to the inlet tube **4114**. In use, gas flows from the inlet tube **4114**, into the intermediate portion **4115(2)**, into the side portions **4115(1)**, and into respective ends of the nasal prong assembly **4120**. Such arrangement provides a symmetrical configuration to improve stability, e.g., with respect to an asymmetric arrangement wherein an inlet tube is connected to one end of the nasal prong assembly. In addition, such arrangement provides flexibility to accommodate different sleep positions, e.g., side of head, back of head, etc.

In an alternative embodiment, the tube entry point may be relocated to the front of the frame for the nasal prong assembly, which may eliminate the need for plugs, seal rings, etc. In yet another embodiment, a central soft tube connection may be incorporated into the nasal prong assembly. The soft tube connection may be structured to accommodate flexibility and movement (e.g., increased decoupling of forces) and may be molded to avoid kinking or reduction of airflow.

FIG. **5-40** illustrates a nasal prong **4224** according to another embodiment of the present invention. As illustrated, the nasal prong **4224** is one size larger than the typically recommended size. The next larger size prong **4224** may be used by educated patients to improve stability as the prong is larger (larger head portion and/or stalk) and requires more force to bend or deform it. In addition, the next larger size prong **4224** may improve seal and may improve comfort as the next larger size prong provides a suspension system that allows looser headgear. In an embodiment, at least the head portion of the prong **4224** may include a frosted surface finish to improve comfort, e.g., frosted surface finish like a lubricated joint that allows sliding.

FIG. **5-41** illustrates a nasal prong assembly **4320** and air delivery conduit **4314** according to another embodiment of the present invention. In the illustrated embodiment, the air delivery conduit **4314** is in the form of spiral tubing, e.g., similar to spiral configuration of a telephone cord. The use of such spiral tubing **4314** may improve stability and help reduce the drag of the tubing on the nasal prong assembly **4320** in use.

In the illustrated embodiment, the spiral tubing **4314** is provided to one end of the nasal prong assembly **4320** for delivering pressurized breathable gas. In an embodiment, the spiral tubing **4314** may be spring loaded or biased to keep the tubing compact and neat and to prevent tangling.

The spiral tubing **4314** may be particularly advantageous for use with such nasal prong assembly **4320**. Specifically, because tubing for the nasal prong assembly is asymmetric or provided to only one side of the nasal prong assembly, typical elongated tubing (e.g., 2 m elongate tubing) may provide enough pass to pull the nasal prong arrangement sideways (e.g., when the patient moves around in bed) which may break the seal between the nasal prongs and the patient's nares. However, the spiral tubing **4314** provides a flexible arrangement that allows sufficient extension and retraction of the tubing in use. This arrangement reduces tube drag and effectively decouples the tubing from the nasal prong assembly to prevent breaking of the seal.

1.6.10 Foam Prong

In an alternative embodiment, at least a portion of the prong may be constructed of a foam material. For example, the entire head portion of the prong may be constructed of a foam material, and provide a foam contact surface to interface with the patient's nasal passages. The foam head portion may provide grip, warming sensation, and/or improved comfort in use.

1.6.11 Question-Mark Shaped Prong

In an alternative embodiment, side walls of the prong may include a question-mark or sickle shaped configuration.

Alternative Embodiment Nasal Prongs

As shown in FIGS. **16-1** to **16-12**, each nasal prong **5024** of nasal prong assembly **5020** includes a head portion **5025** adapted to seal and/or sealingly communicate with a respective patient nasal passage and a column or stalk **5027** that interconnects the head portion **5025** with a gusset **5022**.

In the illustrated embodiment, each head portion **5025** includes a dual or double-wall arrangement including an inner wall **5026** (inner membrane or support membrane) and an outer wall **5028** (outer membrane or sealing membrane) that surrounds the inner wall **5026**. The outer wall **5028** may be relatively thin (e.g., 0.35 mm) with respect to the inner wall **5026** (e.g., 0.75 mm) to conform to the shape of the patient's nose and provide a more compliant seal.

The stalk **5022** may be relatively short (e.g., about 2-8 mm, e.g., 5.1 mm), e.g., due to flexibility provided by the gusset **5022**.

1.7 Other Forms of Interfacing Structure

In other forms of the invention, alternative interfacing structures may be used. For example, a nasal cradle as described in International Patent Application PCT/AU2007/001051, the contents of which are hereby incorporated by cross-reference.

Other alternative forms of interfacing structure could be as described in U.S. Pat. No. 4,782,832 (Trimble et al.), U.S. Pat. No. 5,724,965 (Handke et al.), U.S. Pat. No. 6,119,694 (Correa et al.), U.S. Pat. No. 6,431,172 (Bordewick), and International Patent Application WO 2000/74758 (Lovell et al.), the contents of each of which is hereby incorporated by cross-reference.

2 Positioning, Suspension & Stabilising

2.1 Introduction

A patient interface in accordance with an embodiment of the invention provides a structure for suitable positioning, suspension and stabilizing of the interfacing portion of the patient interface at an entrance to the airways of the patient. This structure includes the stalks of the nasal prongs, the gusset portion, the frame and headgear with stabilizers. The structure as a whole may be regarded as positioning the interfacing portions. The stalks of the nasal prongs, and the gusset portion together function as a form of suspension system. The headgear and stabilizers form a structure that resists bending (for example from tube drag) and yet is flexible to conform to different facial geometries, or to move in response to other potentially disruptive forces. In combination with the suspension system, a greater range of movement of a mask system in accordance with an embodiment of the invention can be accommodated without disrupting the seal than in prior art mask systems.

A frame in accordance with an embodiment of the present invention serves a number of functions, including serving as a connection point to which the gusset, headgear stabilizers and elbow may be connected. A given functional feature may reside in different structures. For example, the stabilizing portion of headgear may be formed as part of a frame either additionally or alternatively.

2.2 Suspension System

Stalks

As shown in FIG. **4-1**, each prong **24** may include a trampoline-like suspension system at both ends of the stalk **27**, such as described in WO 2006/130903. Specifically, each prong **24** may include an upper trampoline-like suspension system **29** between the head portion **25** and the stalk **27**, and a lower trampoline-like suspension system **31** between the stalk **27** and the base **22**. The upper and lower trampoline-like suspension systems **29**, **31** act as a universal mechanism to articulate and align the head portion **25** to the patient's alar and nasolabial angles, self-adjust the stalk length to suit the patient's nasolabial height, and/or provide a comfortable sealing force to the nares. That is, the upper and lower trampoline-like suspension systems **29**, **31** allow rotation of the stalk **27** relative to both the head portion **25** and the base **22**, and allow reduction in height of the head portion **25** relative to the base **22**. For example, a relatively thin base may allow the stalk to sink into the base and/or rotate relative to the base (e.g., like a ball joint), and the head portion may deform and sink into the stalk (e.g., like a ball joint). Such compliance and flexibility in rotation and height allows the range of overall length to be effectively increased or decreased a great deal to allow for accommodation of different geometries.

In an embodiment, the height H of the stalk **27** may be between 5-15 mm, e.g., 7 mm, 8 mm, 9 mm, 12 mm, etc.

In an alternative embodiment, as shown in FIG. **4-2**, the lower trampoline-like suspension system **31** may include a square edge, e.g., square edge between bottom of stalk **27** and base **22**, to provide a suitable collapsing point for the prong **24** on the base **22**. The square edge may bring the center of articulation down towards the base, which may provide more articulation for a particular height of stalk **27**.

Gusset

As best shown in FIGS. **16-5**, **16-9**, and **16-12**, the gusset **5022** of nasal prong assembly **5020** includes a base **5023.1** adapted to support the nasal prongs **5024**, lateral side walls **5023.2**, an outer side wall **5023.3** (adapted to face away from the patient's face in use), and an inner side wall **5023.4** (adapted to face towards and/or contact the patient's face in use).

The gusset **5022** provides structure that creates an axial force to enhance axial or vertical movement (e.g., gusset and prongs (e.g., prong compression) together can move axially or vertically up to about 17 mm), and provide contact with the patient's upper lip, and create an axial force to enhance the nasal prong seal. The gusset also allows lateral movement to enhance stability while maintaining a sufficient seal with an acceptable amount of leak to maintain a sufficient seal (e.g., gusset and prongs (e.g., prong flexibility and dual wall movement) together can move laterally up to about 7-10 mm total with less than 0.5 L/min leak), provides a trampoline like base due to a relatively thin base (e.g., 0.75 mm) which allows articulation and extra flexibility of the nasal prongs, provides compressibility, and provides a wide range of movement of fit a large range of patients.

The dual wall nasal prongs in combination with the gusset enhances the lateral movement of the nasal prong assembly. Also, each nasal prong may include an upper trampoline-like suspension system between the head portion and the stalk, and a lower trampoline-like suspension system between the stalk and the gusset base, which allows rotation of the stalk relative to both the head portion and the gusset base, and allow reduction in height of the head portion relative to the gusset base (e.g., thin gusset base allows retraction of the stalk into the base).

The gusset increases the range of adjustability to substantially prevent overtightening of the headgear, e.g., gusset can compress axially to absorb headgear tension.

As illustrated in FIGS. **16-5**, **16-9**, and **16-12**, the upper portion of the gusset (e.g., base) includes a relatively thinner wall thickness than the lower portion of the gusset (e.g., lower portion of the side walls). In an exemplary embodiment, the wall thickness of the upper portion of the gusset is about 0.75 mm, and the wall thickness of the lower portion of the gusset is about 1.5 mm. However, other suitable wall thicknesses of the gusset are possible, e.g., to adjust rigidity or springiness. For example, in an alternative embodiment, the gusset may include 0.75 mm overall wall thickness, with selected portions of the gusset including stiffening members (e.g., ribs) to add rigidity.

As shown in the side view of FIG. **16-9**, the gusset **5022** provides a wedge like cross-section (e.g., wedge angle α of about 15-45° (e.g., 30°) as shown in FIG. **16-9**) in which the inner side wall **5023.4** includes a larger surface area than the outer side wall **5023.3**. The larger surface area of the inner side wall **5023.4** is structured to contact with the patient's upper lip and tilt the frame and elbow away from the patient's chin and mouth. In addition, this arrangement moves the harder frame edge away from the patient's lip and moves the seal into the patient's nose. The inner side wall **5023.4** may be contoured to match the contour of the patient's upper lip. However, the gusset may have other suitable shapes.

As shown in the front view of FIGS. **16-4** and **16-12**, the gusset **5022** provides a generally V-shaped cross-section in order to angle the prongs in the correct orientation with respect to the patient's nose.

Combination of Pillows and Gusset

A suspension system combination of pillows and gusset in accordance with an embodiment of the present invention provides significant improvement over related and prior pillows. To facilitate an understanding of the nature of the improvement, it is helpful to consider the following:

To effect an adequate seal against a surface, a system can present an interfacing component (e.g. the top portion or head of the pillow) against the face (or surface of the nose) with an appropriate force that restricts the flow of air between the surface of the face and that of the interfacing component. An unnecessarily high level of force is both uncomfortable and unhealthy—with a range of symptoms from red marks to sores and skin necrosis. Most mask systems use a flexible cushioning material positioned against the skin and located between the skin and more rigid components of the mask. The cushioning component may be modeled mechanically as one or more springs.

Generally the spring arrangements of cushions in consideration have a range of possible compression before they are fully compressed or "bottomed out". Once fully compressed, a cushion will generally have little "cushioning" effect, and simply transfer to the face whatever force has been established through headgear tension. We have discovered that it is desirable for improved comfort and seal to provide for significantly more movement before a cushion is fully compressed. As will be presently described, prior nasal pillow arrangements in masks of the presently contemplated type (e.g., Puritan Bennett Adam's Circuit, ResMed Mirage Swift, Innomed Bravo, Respironics Optilife, Fisher & Paykel Opus) provide from about 1 mm to about 6 mm vertical movement, whereas a nasal pillows system according to an embodiment of the present invention can provide up to about 10 mm vertical movement before fully compressing the pillows.

FIG. **23** illustrates the difference between different nasal pillow mask systems. Three mask systems are shown. Each mask system tested generally provides two regions, a flatter region and a steep region. In the first, flatter region, the force on the face transmitted through the pillow increases gradually as the spring is further compressed. Once the spring is fully compressed, the force on the face has a much more significant rate of increase. Of the nasal pillow masks tested, the Puritan-Bennet BREEZE mask system allows approximately 2 mm of compression before the pillow is fully compressed and the force on the face starts to significantly increase. The ResMed SWIFT II allows approximately 6-7 mm of compression before the force on the face starts to increase more significantly. Other mask systems tested lie between the BREEZE and SWIFT masks. A mask system in accordance with an embodiment of the present invention allows approximately 9-10 mm compression before the force on the face starts to increase more significantly.

We have also discovered that comfort and seal of a nasal pillows mask system can be improved if it can accommodated greater lateral movement (e.g., left to right, right to left) without breaking a seal than that provided by known nasal pillows mask systems. For example, providing greater lateral movement facilitates side sleeping. A mask system in accordance with an embodiment of the present invention provides approximately five times the lateral movement of SWIFT II without unacceptably leaking.

FIG. **24** shows the amount of leak measured for the present example and the ResMed SWIFT nasal pillow system when subject to lateral movement. The amount of leak increases with the amount of lateral movement. However, since the present example is much more accommodating of movement than the SWIFT, at a leak level of approximately 2 L/min, approximately 5 mm of total lateral movement can be accommodated with the present example compared to approximately 1 mm for the SWIFT mask. The values determined in this test are dependent on the test rig, and in another test rig, different values may result. Furthermore, the choice of 2 L/min to measure the amount of movement is somewhat arbitrary and intended merely to illustrate the advantages of the present example.

FIG. **25***a* to **25***g* show portions of nasal pillow systems including a range of prior art nasal pillows and the present example (FIG. **25***g*). In particular, they illustrate the portions of the pillows that provide (vertical) compression and lateral movement. As discussed above, the performance of the different nasal pillows may be modeled as a number of mechanical springs. The spring constant for a particular spring may be, amongst other things, a function of the material's inherent resilience, the thickness of the part, a radius of curvature, a configuration (e.g., is the spring a being bent like a cantilever or compressed along its length) as well as the properties of surrounding components. In the following commentary, the shortcomings of prior nasal pillows will be discussed as well as how the present example leads to an improved result.

FIG. **25***a* shows a portion of a nasal pillow from the Puritan-Bennet BREEZE mask. The pillow includes three apparent corrugations as shown, however, the pillow is mounted in a rigid frame between the bottom two corrugations, hence the only movement possible in use is that which is afforded by the flexibility of the regions between the top two corrugations, marked as "flexing" in FIG. **25***a*. We estimate that approximately 2 mm of compression can be provided by the BREEZE pillow before it is fully compressed. It is noted that the radius of curvature of the first curve **25***a*-**2** and second curve **25***a*-**4** is approximately similar.

It is noted that U.S. Pat. No. 6,431,172 (Bordewick) appears to illustrate a nasal pillow similar to the BREEZE nasal pillow, however instead of being mounted on a rigid support, it is mounted on an inflatable plenum chamber. As far as we are aware, no commercial sample was ever produced and hence we are unable to test it. Since the base region is described as "entirely flaccid" and "not effective in transmitting forces between nares elements and rigid support" we expect it not to have any "springiness" (or a spring constant with a value of zero).

FIG. **25***b* shows a cross-sectional profile of the ResMed SWIFT I and SWIFT II nasal pillows system. As illustrated, the "head" of the pillow can compress approximately 6 mm before it reaches the base. The first curved region **25***b*-**2** has a generally similar radius as the second curved region **25***b*-**4**, however because the second curved region **25***b*-**4** is adjacent a much stiffer platform (not shown), the first curved region **25***b*-**2** is more flexible than the second curved region **25***b*-**4**.

FIG. **25***c* illustrates the Fisher & Paykel OPUS nasal pillow. This nasal pillow has a relatively inflexible stalk region. The only compression that is provided is by collapse and buckling of the pillow head or collapse of the stalk base. Because collapse and buckling are unpredictable, this pillow seals very poorly.

FIG. **25***d* illustrates the Respironics OPTILIFE nasal pillow. The corresponding first and second curved regions of this pillow **25***d*-**2** and **25***d*-**4** have approximately similar radii. The first (**25***d*-**2**) of these two regions is more flexible, in use, very little flexing of the second region **25***d*-**4** appears to occur. Approximately 5 mm compression may be achieved before the stalk is fully compressed. Since the rest of the OPTILIFE pillow is relatively stiff, further compression leads to a significant increase in force. Note that the sidewall of the pillow base region is located below the head region hence, once the stalk region is compressed (~5 mm) further compression may only be obtained by buckling the pillow.

FIG. **25***e* illustrates the Innomed BRAVO nasal pillow. This pillow appears to provide approximately 7 mm of compression before bottoming out. The pillow has two curved regions **25***e*-**2** and **25***e*-**4**. The second of these two curved regions appears to have a larger radius than the first and we would expect that the region with the larger radius would be more flexible—everything else being equal. However, since the base region to which the pillow is connected is relatively stiff, flexing only occurs at the first region **25***e*-**2**. Other parts (not shown) of the BRAVO nasal pillows mask adjacent the base of the pillows are constructed from a rigid polycarbonate.

A portion of the pillows of the Fisher & Paykel OPUS 2 mask is shown in FIG. **25***f*. The stalk/neck region of the pillow has two curved portions **25***f*-**2** and **25***f*-**4**. Both curved regions appear to have approximately the same radius. The pillow appears to provide approximately 6 mm of compression before bottoming out. Furthermore, it is noted that the base region **25***f*-**6** of the pillow, is similarly configured to the Respironics OPTILIFE nasal pillow. Hence, upon compression of the pillow beyond that provided by the neck region of the stalk can only be provided by buckling the pillow, or at least attempting to compress it along its length.

FIG. **25***g* shows a portion of a nasal pillow in accordance with an example of the invention. First curved region **25***g*-**2** provides compression of the pillow. Second curved region **25***g*-**4** has a reduced curvature compared to region **25***g*-**2** and hence is stiffer than region **25***g*-**2**. Nevertheless, flexing can still occur at region **25***g*-**4**. Unlike all the prior art nasal pillow regions discussed thus far, the nasal pillow in accordance with an embodiment of the present invention also includes an additional flexing region **25***g*-**5** located on a flatter, top or "platform" region **25***g*-**8** of the gusset. The platform region **25***g*-**8** of the gusset extends approximately 5 to 10 mm from the point of connection of the stalk to the gusset. When the pillow is compressed, this additional flexing region **25***g*-**5** can bend somewhat like a cantilever. This contrasts with the other nasal pillows which may be subject to buckling forces when further compressed.

As shown in FIG. **25***g*, six flexing regions have been enumerated. These may be named as follows: **25***g*-**1** "single wall pillow", **25***g*-**2** "attachment of pillow to stalk", **25***g*-**3** "stalk", **25***g*-**4** "attachment of stalk to platform", **25***g*-**5** "platform" & **25***g*-**6** "gusset" or "base region". By way of comparison of corresponding regions between the SWIFT and the present example, the relative stiffness of the different regions is shown in FIG. **26**. For example, the stiffness of region **2**, the attachment of the pillow to stalk, is approximately the same in the present example and the ResMed SWIFT. However, in region **4**, the attachment of the stalk to platform is less stiff in the SWIFT than in the present example. While the SWIFT does not have a gusset, a comparison can be made between the barrel/base region of the SWIFT and the gusset of the present example and the result is that the gusset of the present example is significantly less stiff than the barrel/base portion of the SWIFT. There is a direct inverse correspondence between the amount of movement provided by stiffness—the stiffer a spring, the less movement is provided for a given force.

FIG. **27***a* to FIG. **271** show a nasal pillow and gusset assembly in accordance with an embodiment of the invention. Some illustrative dimensions are shown. However, it should be noted that the principles of the invention may be applied to other sizes and shapes. A preferred platform region in accordance with an embodiment of the invention has a thickness of approximately 0.75 mm and is molded from 40 Shore A hardness silicone. Other dimensions are as shown.

For example, as shown in FIGS. **27***a* to **271**, D**1** may be about 3 mm, D**2** may be about 1 mm, D**3** may be about 1 mm, D**4** may be about 5 mm, D**5** may be about 2 mm, D**6** may be about 3 mm, D**7** may be about 4 mm, D**8** may be about 5 mm, D**9** may be about 6 mm, D**10** may be about 0.6 mm at the tip, D**11** may be about 20 mm, D**12** may be about 7 mm, D**13** may be about 5 mm, D**14** may be about 9 mm, D**15** may be about 10 mm, D**16** may be about 25 mm, D**17** may be about 14 mm, D**18** may be about 27°, D**19** may be about 32 mm, D**20** may be about 2 mm, D**21** may be about 21 mm, D**22** may be about 30°, D**23** (the average outer membrane thickness) may be about 0.35 mm, D**24** (the average inner membrane thickness) may be about 0.75 mm, D**25** (the average thickness of the stalk) may be about 0.75 mm, D**26** (the average platform thickness) may be about 0.75 mm, D**27** may be about 9 mm, D**28** may be about 11 mm, D**29** may be about 5 mm, D**30** may be about 73°, D**31** may be a radius of about 12 mm, D**32** may be a radius of about 5 mm, D**33** may be about 54 mm, and D**34** may be about 29 mm. Although specific dimensions are indicated, it is to be understood that these dimensions are merely exemplary and other dimensions are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

As shown in FIG. **27***d*, the gusset includes a top lip stability region. This portion of the gusset lightly rests on the top lip of the patient in use to aid stability of the system. The area is approximately 5 cm^2. When compared to the ResMed SWIFT mask (approximately 3.5 cm^2), OPUS 1 (approximately 2 cm^2) and OPUS 2 (approximately 2.5 cm^2), this region has a relatively larger area, which leads to less pressure on the top lip, and less force concentrations. The exact area in contact with a patient's lip depends on how the mask is positioned in use.

As shown in FIG. **27***d*, the platform region of the gusset is angled at approximately 30° with respect to the base of the gusset. See also FIG. **28** which is a sketch illustrating the pillows and gusset in use. By adopting this angled configuration, the risk of frame contacting the top lip is reduced, improving comfort.

FIG. **29** illustrates a nasal pillow according to an embodiment of the invention (top row) and a prior art arrangement (2nd row). When subject to a compression force (right hand side), as in when in use, a number of regions of the present example, such as the platform region begin to bend and flex. However, the same force on the prior art mask assembly only results in bending of the region the top of the stalk and the head of the pillow.

Another known form of nasal pillow is described in International Patent Application No. PCT/AU2006/000770 (Lubke et al., assigned to ResMed) published as WO 2006/130903. This nasal pillow is particularly suited for an oro-nasal mask. Because the oro-nasal mask includes nasal pillows extending from a mouth cushion, they have a significantly longer stalk region than the nasal pillows discussed above. This long stalk arrangement also provides a significant amount of flexibility and articulation, however this long-stalk arrangement is a different configuration to the present example. In the present example, significant articulation and movement is provided in relatively short stalks when compared to the oro-nasal mask of WO 2006/130903. Furthermore, the corresponding top region of the mouth cushion to which the long-stalk pillows are connected is relatively stiff compared to the top region of the present example.

Gusset to Frame Attachment

As shown in FIGS. **16-1** to **16-12**, the nasal prong assembly **5020** includes a frame contacting portion **5029** that extends from the lower end of the gusset **5022**, and is structured to be removably and replaceably attached to a frame **5030** (e.g., see FIGS. **15-1** to **15-12**), e.g., push-in type fit, tongue/groove mechanical interlock. As illustrated, the frame channel **5033** of the frame **5030** is provided along a curve (e.g., see FIG. **15-7**).

As best shown in FIGS. **16-5** and **16-6**, the frame contacting portion **5029** includes an end portion **5029.1** with a sealing lip **5029.2**. The end portion **5029.1** is adapted to be easily inserted and retained within the frame channel **5033** (end portion **5029.1** may be tapered to facilitate insertion). The sealing lip **5029.2** provides a seal around the perimeter of the frame channel **5033** and also in conjunction with the bead **5033.1** (see FIGS. **15-9** and **15-12**) around the frame channel **5033** retains the nasal prong assembly **5020** onto the frame **5030** during use, as shown in FIG. **17**. In addition, such arrangement allows the nasal prong assembly to be easily disassembled from the frame, e.g., for cleaning or replacement.

It is noted that, without the sealing lip **5029.2** or bead **5033.1**, the end portion **5029.1** would still be able to provide a seal just by interference of the end portion **5029.1** and the frame. However, the sealing lip and bead arrangement are structured to allow quite a bit of disassembly of the nasal prong assembly from the frame without any increase in leak. For example, FIG. **16-6-1** illustrates the end portion **5029.1** engaged with the frame **5030** (ideal sealed assembly), and FIG. **16-6-2** illustrates the end portion **5029.1** partly disassembled from the frame **5030** but the sealing lip **5029.2** remains engaged with the bead **5033.1** to maintain seal. In an embodiment, this arrangement may allow the sides of the nasal prong assembly to lift out of the frame a little while the external catches **6029.3** remain fully engaged with the frame **6030** (e.g., see FIG. **16-14-1** described below).

In one form the frame bead **5033.1** has a protrusion in the range of 0.4 mm to 1.2 mm, preferably 0.8 mm. The angle of the underside of the bead is preferably in the range 85° to 95°, preferably 90°. Other protrusion values and angles are possible. More than one bead may also be used.

As shown in FIG. **17**, the sealing lip **5029.2** seals along the inner wall of the frame channel **5033** closest to the internal volume of the frame **5030**. Any air pressure between the end portion **5029.1** and the inner wall of the frame channel **5033** will enhance the seal as the air pressure will force the sealing lip **5029.2** into the inner wall of the frame channel **5033**.

In an embodiment, the end portion **5029.1** of the frame contacting portion **5029** may be sufficiently long (e.g., D**23** is about 5 mm long) to help locate the end portion **5029.1** in the frame channel **5033** before an insertion force is applied to secure the end portion **5029.1** in position. In addition, the end portion **5029.1** may provide only a slight taper so that the end portion **5029.1** is sufficiently thick to aid insertion and/or to create interference in the channel, increasing retention. The end portion **5029.1** may also be very long, e.g., the whole depth of the frame channel, to increase retention. This length may vary around the perimeter of the end portion, e.g., only at the front and back, between protrusions **5629.1** (described below), etc.

In an embodiment, the frame contacting portion **5029** and frame channel **5033** may provide locating features to properly align the nasal prong assembly **5020** with respect to the frame **5030** and prevent askew assembly. For example, the frame contacting portion **5029** may include one or more corners/protrusions (example described below) that are adapted to fit into corresponding recesses provided in the frame channel **5033**. However, other suitable locating arrangements are possible.

FIGS. **16-13-1** to **16-13-7** illustrate a nasal prong assembly **5620** including a frame contacting portion **5629** with one or more protrusions **5629.1** (e.g., four protrusions). When assembled to the frame, the one or more protrusions **5629.1** are adapted to fit into corresponding recesses provided in the frame channel to align the nasal prong assembly **5620** with respect to the frame (e.g., see recesses **5633.1** in frame **5630** in FIGS. **22-1-2** and **22-1-4** described in greater detail below).

FIGS. **16-14-1** to **16-14-3** illustrate a nasal prong assembly **6020** and frame **6030** according to another embodiment of the present invention. In this embodiment, the frame contacting portion **6029** of the nasal prong assembly **6020** includes an external catch or protrusion **6029.3** on opposing sides thereof. When assembled to the frame **6030**, the external catches **6029.3** are adapted to interlock with corresponding openings **6033.1** provided in the frame channel **6033** of the frame **6030**. Such arrangement is structured to improve retention of the nasal prong assembly **6020** to the frame **6030**. In addition, the user can visually confirm that the frame/nasal prong assembly are properly connected. Disassembly is relatively easy because the parts are flexible and soft, e.g., disassemble by peeling/pulling nasal prong assembly out of frame. Also, assembly is relatively easy because the frame is sufficiently rigid, the external catches **6029.3** are sufficiently thick, the frame "window" bar **6033.2** (including thickness t**1** plus t**2** (see FIG. **16-14-2**)) is sufficiently flexible and rigid to stretch and snap into place over the external catch **6029.3** (e.g., see FIGS. **16-14-2**, **16-16-1**, and **16-16-7**). As shown in FIG. **16-16-7**, the bar **6033.2** may include a chamfer c to aid insertion/location of the nasal prong assembly.

FIGS. **16-15-1** to **16-15-10** illustrate the nasal prong assembly **6020**. As illustrated, the nasal prong assembly **6020** includes the gusset **6022**, the pair of nasal prongs **6024** provided to the gusset **6022**, and the frame contacting portion **6029** extending from the lower end of the gusset **6022**. The frame contacting portion **6029** includes four alignment protrusions **6029.1** and a sealing lip **6029.2** around its perimeter as described above. In addition, opposing sides of the frame contacting portion **6029** include the external catch **6029.3** which protrudes outwardly from the bottom edge.

FIGS. **16-16-1** to **16-16-8** illustrate the frame **6030**. As illustrated, the frame **6030** includes a main body **6032** with a channel **6033** to retain the nasal prong assembly **6020** and a tube portion **6035** to retain the elbow. Cylindrical connectors **6034** are provided to respective sides of the main body **6032** for assembling headgear yoke. Yoke to frame assembly and elbow to frame assembly is described in greater detail below.

Opposing sides of the frame channel **6033** include the opening **6033.1**, which extends from the channel to the frame exterior. When the frame contacting portion **6029** is inserted and retained within the frame channel **6033**, the external catches **6029.3** protrude through respective openings **6033.1** to the frame exterior. As illustrated, recessed portions **6032.1** are provided to the frame exterior adjacent each opening **6033.1**, e.g., for tooling. The recessed portions

6032.1 also allow visual feedback of complete assembly and facilitate access to the catches 6029.1 for assembly, e.g., if the catches get stuck.

As shown in FIG. 16-16-7, dimension d is sufficient to allow clearance for the contacting portion 6029 of the nasal prong assembly. This allows the nasal prong assembly to be pushed in far enough for the catch 6029.3 to snap past the window bar 6033.2. For the same reason, the catch 6029.3 has been design with enough clearance between it and the gusset 6022.

FIG. 16-14-3 illustrates a patient interface 6010 including frame 6030, nasal prong assembly 6020, elbow 6040, and headgear including headgear yoke 6055 and straps 6053 (headgear described in greater detail below).

In an embodiment, the nasal prong assembly may be attached to the frame in either of two orientations (180° with respect to one another) and then the headgear must be correctly attached to ensure correct orientation of the nasal prong assembly with respect to the patient's face in use (e.g., headgear and frame/nasal prong assembly may include marking to ensure proper assembly/orientation). However, if the headgear is first attached to the frame, then the nasal prong assembly must be correctly oriented and attached to the frame (same markings apply).

In an alternative embodiment, the patient interface may be structured such that the nasal prong assembly may be attached to the frame in only one way and the headgear may be attached to the frame in only one way in order to ensure correct assembly/orientation (e.g., use mechanical constraints such that left side frame to left side yoke only and right side frame to right side yoke only).

The curved end of the gusset portion (see for example FIGS. 16-4 and 27*e*) result in the centre of gravity of the nasal mask system being closer to the face of the patient, making the system more stable.

Other gusset to frame mechanisms may be used. See for example the disclosure of International Patent Application PCT/AU03/00458 published as WO 03/090827. Other mechanisms may also be used, for example that used in the cushion-to-frame mechanism of the Fisher & Paykel OPUS. In this case, the orientation of the bead may be perpendicular to the orientation of the illustrated embodiment. In another form, the cushion and frame may be comolded and hence no gusset/cushion to frame mechanism would be required.

FIGS. 16-17 to 16-39 illustrate gusset-to-frame attachment mechanisms according to alternative embodiments of the present invention.

FIG. 16-17 illustrates an arrangement similar to that shown in FIGS. 16-14-1 to 16-16-8, i.e., nasal prong assembly 8020 including external catch 8029.3 adapted to interlock with corresponding opening 8033.1 in frame 8030. In contrast, the frame 8030 includes little to no recessed portion 8032.1 (e.g., unlike elongated recessed portion 6032.1 in FIGS. 16-14-1 to 16-14-3) adjacent each opening 8033.1.

FIGS. 16-18-1 and 16-18-2 illustrate a nasal prong assembly 8120 including two external catches 8129.3 on each opposing side thereof that are adapted to interlock with corresponding openings 8133.1 in the frame 8130. As shown in FIG. 16-18-3, the frame 8130 may include ribs 8136 along the frame channel 8133 (e.g., on opposing ends and sides of the channel), e.g., to add rigidity to the frame.

FIG. 16-19 illustrates a single internal catch arrangement. In the illustrated embodiment, the nasal prong assembly 8220 includes a catch on opposing sides thereof (not visible) that are adapted to interlock with a corresponding internal recess in the frame 8230 (only a protrusion 8238 providing such internal recess being shown).

FIG. 16-20 illustrates the frame contacting portion 8329 of a nasal prong assembly including an end portion 8329.1 with a sealing lip 8329.2. As illustrated, the end portion 8329.1 is sufficiently wide to always provide an interference fit in the channel 8333 of the frame 8330. The bead 8333.1 around the frame channel 8333 also helps retain the nasal prong assembly onto the frame 8330. In addition, the thickness of the outer wall 8339 may be increased to enhance interference with the frame contacting portion. In an embodiment, the frame contacting portion 8329 may provide about 0.4 mm of interference with the channel 8333.

FIG. 16-21 illustrates a frame 8430 in which an inner wall portion 8435 is thickened around its perimeter, e.g., to add rigidity or stiffness. As illustrated, the frame undercut or elbow-to-frame cutout 8437 for retaining the elbow 8440 (e.g., with a snap fit) is maintained where necessary. In an embodiment, a clearance c of about 0.2-0.3 mm may be provided between the elbow 8440 and frame 8430 when connected.

FIG. 16-22 illustrates a frame 8530 in which the snap length of the elbow 8540 is increased to stiffen the inner wall 8535 of the frame 8530. That is, the location of the frame undercut or elbow-to-frame cutout 8537 for retaining the elbow 8540 (e.g., with a snap fit) is moved further into the frame 8530.

FIG. 16-23 illustrates a frame 8630 in which the height of the inner wall 8635 is increased to match the height of the frame contacting portion 8629 of a nasal prong assembly. In an embodiment, the height of the inner wall may be increased in selected portions of the frame, e.g., only at opposing front and back portions of the frame.

FIG. 16-24 illustrates a frame 8730 in which the height of the inner wall 8735 is increased to greater than the height of the frame contacting portion 8729 of a nasal prong assembly. In addition, a hook portion 8739 is provided to the inner wall 8735 that is adapted to lock the frame contacting portion 8729 within the frame channel. In an embodiment, the increased height of the inner wall and hook portion may be provided in selected portions of the frame, e.g., only at opposing front and back portions of the frame.

FIG. 16-25 illustrates a frame contacting portion 8829 of a nasal prong assembly in which the stiffness of the sealing lip 8829.2 is increased by thickening the lip. For example, the sealing lip 8829.2 may be thickened along inner portion A, along upper end portion B, and/or along lower portion C. In another embodiment, the stiffness of the sealing lip 8829.2 may be increased by reducing the length of the lip from the frame contacting portion.

FIG. 16-26 illustrates a frame contacting portion 8929 in which the length is increased and the sealing lip 8929.2 is moved downwards, e.g., to lower the engagement point with the frame 8930. To accommodate such frame contacting portion, the bead 8933.1 around the frame channel 8933 is moved downwards, and any frame ribs within the channel are removed or lowered.

FIG. 16-27 illustrates a frame contacting portion 9029 with two sealing lips 9029.2 in series adapted to interface with respective beads 9033.1 along the inner wall of the frame 9030.

FIG. 16-28 illustrates a frame contacting portion 9129 with a sealing lip 9129.2 adapted to interface with a bead 9133.1 along an inner wall of the frame 9130 and a recessed portion 9129.5 adapted to interface with a bead 9133.2 along an outer wall of the frame 9130. The positioning and/or configuration of each lip, recessed portion, and bead may vary.

For example, in FIG. **16-29**, the bead **9133.2** along an outer wall of the frame **9130** may be positioned more downwards within the frame channel and the corresponding recessed portion **9129.5** may be positioned more downwards along the frame contacting portion **9129**. In FIG. **16-30**, the frame contacting portion **9129** includes a sealing lip **9129.2** adapted to interface with a bead **9133.1** along an inner wall of the frame **9130** and a second sealing lip **9129.3** adapted to interface with a bead **9133.2** along an outer wall of the frame **9130**. In FIG. **16-31**, the frame contacting portion **9129** includes a sealing lip **9129.2** adapted to interface with an inner wall of the frame **9130** and a recessed portion **9129.5** adapted to interface with a bead **9133.2** along an outer wall of the frame **9130**.

FIGS. **16-32** and **16-33** illustrates a frame contacting portion **9229** with a sealing lip **9229.2** adapted to interface with a bead **9233.1** along an inner wall of the frame **9230** and a non-slip interface **9229.5** adapted to interface with an outer wall of the frame **9230**. The non-slip interface may be barbed (FIG. **16-32**), ribbed (FIG. **16-33**), or zig-zag, for example.

In another embodiment, vertical ribs along the channel of the frame and/or along the frame contacting portion of the nasal prong assembly may be used to create interference for securing the frame contacting portion within the frame channel.

FIG. **16-34-1** illustrates a frame contacting portion **9329** in which the flange length or end portion **9329.1** is extended, e.g., to aid insertion into the frame channel, to create interference in the frame channel, to increase retention in the frame channel. This extended length may vary around the perimeter of the frame contacting portion, e.g., to accommodate frame ribs within the frame channel. In an embodiment, the extended end portion **9329.1** may include a second sealing lip **9329.3** as shown in FIG. **16-34-2**.

FIG. **16-35** illustrates a frame **9330** including a frame channel **9333** adapted to accommodate a frame contacting portion of a nasal prong assembly. As illustrated, opposing frame ribs A, B, C, and D are provided at the base of the frame channel **9333**, e.g., to add rigidity to the frame. In an embodiment, one or more of the opposing frame ribs A, B, C, and D may be removed so that the frame channel can accommodate an extended frame contacting portion **9329** such as that shown in FIGS. **16-34-1** or **16-34-2**. Alternatively, the frame contacting portion **9329** may be structured to accommodate one or more of the opposing frame ribs A, B, C, and D.

For example, the frame may only include opposing frame ribs A, and the frame contacting portion may be extended around its perimeter except where the opposing frame ribs A would be located. In another embodiment, the frame may only include opposing frame ribs A and C (see FIG. **16-36** showing frame **9330** with frame ribs A and C only), and the frame contacting portion may be extended around its perimeter except where the opposing frame ribs A and C would be located (see FIG. **16-37** showing frame contacting portion **9329** with cutouts or spaces to accommodate frame ribs A and C). In another embodiment, the frame may only include opposing frame ribs A, B, and D (see FIG. **16-38** showing frame **9330** with frame ribs A, B, and D only), and the frame contacting portion may be extended around its perimeter except where the opposing frame ribs A, B, and D would be located. In this embodiment, the outer wall of the frame may be thickened where opposing frame ribs C are removed further down into the frame channel. In yet another embodiment, the frame may not include any frame ribs, and the frame contacting portion may be extended around its entire perimeter.

FIG. **16-39** illustrates a frame contacting portion **9429** of a nasal prong assembly in which the stiffness of the sealing lip **9429.2** is increased by filling a gap with silicone **9429.8**.

Assembly of Prongs and Gusset

As shown in FIGS. **16-1** to **16-12**, the nasal prong assembly **5020** (e.g., constructed of silicone (e.g., 40 shore A silicone)) includes a gusset **5022** and a pair of nasal prongs **5024** provided to the gusset **5022**. The gusset **5022** provides a trampoline-like base which allows movement or flexibility to isolate external forces from the seal (e.g., frame movement does not affect nasal prong seal) and enhance stability, seal, and comfort, as described.

In an embodiment, one or more portions of the exterior surface of the nasal prong assembly **5020** (e.g., the entire exterior surface) may have a frosted or fine surface finish (e.g., sand blasted) in order to reduce dust collection.

In an embodiment of the nasal prong assembly (see FIGS. **16-1** to **16-12**), D**1** may be about 25-35 mm, e.g., 32.3 mm, D**2** may be about 15-25 mm, e.g., 20.6 mm, D**3** may be about 1-2 mm, e.g., 1.5 mm, D**4** may be about 25-35°, e.g., 30°, D**5** may be about 10-20 mm, e.g., 13.63 mm, D**6** may be about 20-30°, e.g., 27°, D**7** may be about 5-10 mm, e.g., 7.98 mm, D**8** may be about 5-15 mm, e.g., 10.29 mm, D**9** may be about 15-25 mm, e.g., 20.1 mm, D**10** may be about 5-10 mm, e.g., 6.99 mm, D**11** may be about 3-8 mm, e.g., 4.63 mm, D**12** may be about 20-30 mm, e.g., 25.1 mm, D**13** may be about 5-10 mm, e.g., 8.87 mm, D**14** may be about 5-15 mm, e.g., 11.14 mm, D**15** may be about 2-8 mm, e.g., 5.1 mm, D**16** may be about 0.5-1 mm, e.g., 0.75 mm, D**17** may be about 0.5-1 mm, e.g., 0.75 mm, D**18** may be about 65-75°, e.g., 72.5°, D**19** may be about 50-60 mm, e.g., 54.37 mm, and D**20** may be about 25-35 mm, e.g., 28.6 mm, D**21** may be about 2-3 mm, e.g., 2.2 mm, D**22** may be about 2-4 mm, e.g., 3 mm, and D**23** may be about 4-5 mm, e.g., 4.8 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

In an embodiment, the nasal prong assembly may be provided in multiple sizes, e.g., small, medium, and large.

2.3 Frame

As shown in FIGS. **15-1** to **15-12**, the frame **5030** includes a main body **5032** and tubular connectors **5034** provided to respective sides of the main body **5032**. As illustrated, the frame **5030** provides a relatively a narrow width across the patient's face, e.g., about 45-55 mm (e.g., 48 or 49 mm).

Referring to FIGS. **15-8** and **15-10**, the main body **5032** includes a channel **5033** structured to retain the nasal prong assembly **5020** and an open-ended tube portion **5035** structured to retain the elbow **5040**. The open-ended tube portion **5035** protrudes from a frame opening rearwards into an internal volume of the frame. Attachment of the elbow **5040** to the frame **5030** is described in greater detail below.

Each connector **5034** of the frame includes a cavity **5036** having structure to retain respective headgear yoke **5055** of the headgear **5050**. In addition, the exterior surface of each connector **5034** includes one or more locking bumps **5038** (e.g., three locking bumps or six locking bumps) adapted to engage ratchet teeth of respective yoke **5055**. Attachment of the headgear yoke **5055** to the frame **5030** is described in greater detail below.

The frame **5030** is constructed of a relatively semi-rigid or soft plastic material (e.g., hard silicone (e.g., 30-80 shore A silicone, preferably 70 shore A silicone, or about 60 or 80 shore A silicone), TPE, thermoplastic polyurethanes). As a result, the frame **5030** is relatively softer and more flexible than the relatively hard plastic material of the elbow **5040** and the yokes **5055** of the headgear **5050**. The flexibility of the frame may be adjusted, e.g., frame may have different degrees of flexibility. However, it should be appreciated that the frame may be constructed of other suitable materials, e.g., harder plastic material. In addition, the frame may have thicker wall section to add hardness. For example, the hardness of the frame material could extend to the Shore D hardness scale in the range of 45 to 85, or on the Rockwell R scale in the range of 50 to 100. It could be made from rubbers, polyurethanes, polyesters, PTFE, polypropylenes and other plastics.

A frame constructed of silicone provides an arrangement that is easier to seal (e.g., with the elbow), and provides no squeak in use (e.g., when elbow/yokes rotated with respect to frame), without requiring an additional part and with reduced leak (e.g., effectively zero leak).

In an embodiment of the frame (see FIGS. **15-1** to **15-12**), D**1** may be about 25-35 mm, e.g., 31.7 mm, D**2** may be about 15-25 mm, e.g., 19.7 mm, D**3** may be about 45-55 mm, e.g., 48 mm, D**4** may be about 35-45 mm, e.g., 39 mm, D**5** may be about 25-35 mm, e.g., 28 mm, D**6** may be about 20-30 mm, e.g., 26.76 mm, D**7** may be about 10-20 mm, e.g., 16.9 mm, and D**8** may be about 15-25 mm, e.g., 21.06 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

Flexibility of the frame allows a given mask system to accommodate a range of different facial geometries, for example ranging from narrower, pointed faces (the so-called “crocodile” or “alligator” shape) to the wider, flatter shape (the so-called “panda” shape). The soft frame is also aesthetically nicer and soft to touch. The outside surface finish conceals internal details (ribs) and reduces dust. A surface finish may be applied to inside surfaces also.

2.4 Adjustment

Naso-Labial Angular Adjustment/Yoke to Frame

2.4.1 Headgear/Yoke to Frame Interface

In an illustrated embodiment, headgear is attached to the frame **5030** via headgear yoke **5055** (e.g., see FIGS. **19-1** to **19-5**). The headgear yoke **5055** includes a yoke to frame interface **5085** that is structured to provide easy assembly to and disassembly from the frame **5030** (e.g., clear and intuitive assembly, tactile feedback of engagement, easy disassembly for cleaning), retain the frame **5030** during use (e.g., prevent accidental disassembly during use), provide rotation relative to the frame **5030**, and provide a friction element to provide sufficient rotational torque (e.g., to reduce tube drag, provide tactile/audible feedback). In addition, rotation of the frame relative to the yokes does not effect impedance.

The frame and nasal prong assembly attached thereto may be rotated with respect to the yokes positioned on the patient’s head to allow adjustment to suit the nasolabial angle for a large range of patients. In addition, such adjustment allows movement of the nasal prongs to avoid air jetting. Because the rotation point RP (see FIG. **13-2**) of the yoke to frame interface is spaced sufficiently outwardly from the patient’s nose (e.g., with respect to the yoke **55**/frame interface described above), a degree of rotation of the frame may not effect an equal degree of rotation of the nasal prongs, e.g., not 1:1 rotation. For example, a 5° rotation of the frame may effect a 2° rotation of the nasal prongs.

As best shown in FIGS. **19-5** to **19-7**, the yoke to frame interface **5085** includes a rear wall **5085.1**, an annular side wall **5085.2**, and a central hub **5085.3**. The inner edge of the side wall **5085.2** includes a plurality of ratchet teeth **5085.4** to provide friction and tactile feedback with respect to the frame. The central hub **5085.3** is tubular with its interior cored out/vented. The central hub **5085.3** provides snap fingers **5085.5** to retain the interface to the frame **5030** (e.g., three snap fingers), bearing surfaces **5085.6**, and a tip extension **5085.7**. Supporting ribs **5085.8** extend between the central hub **5085.3** and the side wall **5085.2**. In addition, windows **5085.9** are provided in the rear wall **5085.1** to allow molding of the snap fingers **5085.5**.

2.4.2 Frame Attachment

As shown in FIG. **19-8**, the yoke to frame interface **5085** is structured to attach to a respective connector **5034** of the frame **5030**. Each connector **5034** of the frame includes a cavity **5036** having structure to retain respective headgear yoke **5055**, i.e., an annular engagement lip **5037.1**, yoke snap clearance **5037.2** and yoke tip extension hole **5037.3** to accommodate the yoke to frame interface **5085**, and a bearing surface **5037.4**. In addition, the exterior surface of each connector **5034** includes one or more locking bumps **5038** (e.g., three locking bumps) adapted to engage the ratchet teeth **5085.4** of the yoke to frame interface **5085**.

FIGS. **19-9-1** to **19-9-6** illustrate attachment of the yoke to frame interface **5085** to a respective connector **5034** of the frame **5030**. In FIG. **19-9-1**, the tip extension **5085.7** of the yoke to frame interface is inserted past the engagement lip **5037.1** on the frame to begin alignment. In FIG. **19-9-2**, the yoke snap fingers **5085.5** and frame engagement lip **5037.1** contact slightly before contact of the frame bumps **5038** and yoke ratchet teeth **5085.4**, and the connector **5034** may pull in a little (as indicated by the arrows). In FIG. **19-9-3**, as the yoke is inserted further, the frame engagement lip **5037.1** is displaced down and the connector **5034** expands (as indicated by the arrows). Also, the ratchet teeth **5084.4** engage with the frame bumps **5038**. In FIG. **19-9-4**, the frame engagement lip **5037.1** is folded down almost flat inside the yoke snap clearance **5037.2**, and expansion of the frame connector **5034** is limited by the surrounding yoke side wall **5085.2** (as indicated by the arrows). In FIG. **19-9-5**, the front face of the yoke snap fingers **5085.5** and tip extension **5085.7** bottom out inside the yoke tip extension hole **5037.3** (e.g., yoke compressed inwards about 1.6 mm beyond nominal position), which provides sufficient space to allow the frame engagement lip **5037.1** to relax or resiliently recover to its original position (as indicated by the arrows). That is, the yoke snap clearance **5037.2** and the yoke tip extension hole **5037.2** is sufficiently long to provide sufficient space for the frame engagement lip **5037.1** to recover to its nominal position following a natural arc, e.g., resiliently pivot back to its nominal position. In FIG. **19-9-6**, the yoke to frame interface **5085** springs back out to a nominal position when the engagement lip **5037.1** relaxes. As shown in FIG. **19-10**, a clearance C**1** of at least about 0.5 mm is provided between an outer edge of the frame connector **5034** and the yoke to frame interface **5085**.

The snap fingers **5085.5** and tip extension **5085.7** are structured to retain the yoke to the frame, e.g., axial retention and lever retention. In an embodiment, as shown in FIGS. **19-11** and **19-12**, the tip extension **5085.7** has a length D**1** of about 2-4 mm, e.g., 3 mm, each snap finger **5085.5** has a diameter D2 of about 6-8 mm, e.g., 7 mm, each snap finger 5085.5 has width D3 of about 2-5 mm, e.g., 4 mm, and each snap finger 5085.5 provides an engagement face of about 5-15°, e.g., 10°. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

In an embodiment, the yoke 5055 may be pivoted with respect to the frame 5030 without disassembly by an angle D1 of about 5-15°, e.g., due to lever retention and/or frame flexibility.

As shown in FIG. 19-14, the locking bumps 5038 of the frame 5030 and the ratchet teeth 5085.4 of the yoke to frame interface 5085 provide a ratcheting arrangement to lock the frame/nasal prong assembly in an operative position. In addition, the ratcheting arrangement provides a rotation and sufficient torque arrangement to resist tube drag, and prevent the nasal prongs from being rotated out of the patient's nose, rotate relative to the frame and allow adjustment to suit nasolabial angle, and provide tactile feedback to the user with adjustments.

For example, such arrangement allows 360° rotation of the yoke with respect to the frame, provides position locks at 15° increments, and the soft to hard interface (relatively soft frame engages relatively hard yoke) provides tactile feedback to the user with each adjustment. However, the ratchet teeth/locking bumps may be structured to provide other suitable incremental position locks.

The size of the ratchet teeth 5085.4 and locking bumps 5038 may be determined by fitting a maximum number of increments (e.g., 6 to 72 teeth at 60° to 5° increments, e.g., 24 teeth at 15° increments) around a minimum diameter. In an embodiment, the length of tooth engagement (i.e., contact length between locking bump and ratchet tooth) may be determined by the shallowest point of yoke contacting frame on assembly (e.g., about 2 mm).

FIGS. 19-15-1 to 19-15-5 illustrate rotation of the yoke 5055 with respect to the frame 5030, e.g., angle adjustment. FIGS. 19-15-1 and 19-15-2 illustrate a nominal position of the yoke 5044 and frame 5030. In FIG. 19-15-3, the yoke 5055 is rotated about 3.25° from nominal, and the frame locking bumps 5038 are deformed sideways and compressed inwards. In FIG. 19-15-4, the yoke 5055 is rotated about 10.75° from nominal, and the frame locking bumps 5038 are significantly deformed flat by the respective ratchet tooth 5085.4. In FIG. 19-15-5, the yoke 5055 is rotated about 15° from nominal, and the frame locking bumps 5038 spring back to original form in the next ratchet tooth 5085.4.

It should be appreciated that the torque (e.g., to resist tube drag) may be adjusted, e.g., torque increased by adding more locking bumps 5038 to frame connectors 5034. Also, instead of a ratcheting type arrangement, other suitable torque arrangements may be provided, e.g., friction-type, magnetic, etc.

In alternative embodiment, the one or more locking bumps of the frame may be separated by truncated or squared-off teeth to allow for easier rotation of the yoke with respect to the frame. For example, FIGS. 22-1-1 to 22-1-8 illustrate a frame 5630 and each connector 5634 of the frame 5630 includes locking bumps 5638 (e.g., six locking bumps) separated by truncated teeth 5639 (e.g., see FIG. 22-1-7).

The indents 5639.1 between the locking bumps and the truncated teeth make the locking bumps 5638 longer, meaning that the stress and thus wear on these elements is lower. In addition, as shown in FIGS. 22-1-9 and 22-1-10, as the yoke 5655 rotates relative to the frame 5630, each locking bump 5638 is displaced sideways. The indent 5639.1 defines a spring relief feature that provides clearance allowing the locking bump 5638 to completely flex over on itself. This reduces wear on the semi-rigid locking bump 5638 over time. The number of locking bumps 5638 may be adjusted for desired torque. The cavity 5636 of the connector 5634 may be cut out (e.g., by 1 mm) to allow for a snap lock with the central hub 5685.1 of the headgear yoke 5655 for tactile connectivity. Attachment of the headgear yoke 5655 to the frame 5630 is described in greater detail below.

As shown in FIGS. 22-2 and 22-3, the first end portion 5655(1) of each headgear yoke 5655 includes a support arm 5680, a yoke to frame interface 5685 provided to an end of the support arm 5680 and adapted to engage a respective connector 5634 of the frame 5630, and a cheek support 5684 (also referred to as a stability arm).

The yoke to frame interface 5685 is structured to provide easy assembly to and disassembly from the frame 5630 (e.g., clear and intuitive assembly, tactile feedback of engagement, easy disassembly for cleaning), retain the frame 5630 during use (e.g., prevent accidental disassembly during use), provide rotation relative to the frame 5630, and provide a friction element to provide sufficient rotational torque (e.g., to reduce tube drag, provide tactile/audible feedback). Torque is also provided by interference on the "shaft" between the yoke and the frame, not just the ratchet teeth. For example, FIGS. 22-16-1 and 22-16-2 illustrate an embodiment in which the yoke 5655 is structured to have an interference fit on the shaft 5634.1 of the frame 5630 to provide torque additional to the ratchet teeth. In an embodiment, the interference fit may be about 0.4 mm on diameter on the frame shaft, e.g., each d about 0.2 mm in FIG. 22-16-2.

The yoke connection involved in the yoke to frame interface 5685 consists primarily of an annular side wall 5685.2, rear wall 5685.3 and central hub 5685.1 (e.g., see FIGS. 22-4 to 22-7-8).

The inner radius of side wall 5685.2 has multiple ratchet teeth 5685.4 (e.g., 3, 4, 5, or more teeth) to provide friction while allowing for some rotation of the frame with respect to the yoke (e.g., see FIGS. 22-6 and 22-7-8). It should be appreciated that there can be multiple embodiments of ratchet teeth/locking bumps on the yoke/frame, e.g., 24 teeth/bumps on frame or yoke adapted to engage 3 or more teeth/bumps on the other of the frame or yoke. The rotation means the headgear can adapt more readily to the movement of the patient during sleep. Additionally, on the interfacing side of the yoke (i.e., the side of the yoke that sits closest to the patient's skin), the side wall 5685.2 extends radially inwards (e.g., by 3 mm) to form a generally C-shaped engagement lip 5685.5 (e.g., see FIGS. 22-4, 22-6, and 22-7-6). This is to allow for a locked horizontally sliding connection with the frame connector 5634 (direction of sliding connection shown in FIG. 22-2) that inhibits lateral movement of the yoke and frame so as to prevent the accidental disassembly of the yoke to frame interface 5685 during use. The tips 5685.5(1) of the C-shaped engagement lip 5685.5 are convexly curved to provide a lead-in for the frame connector shaft or base 5634.1, thereby enabling alignment during assembly (e.g., see FIGS. 22-4 and 22-7-6). The width between these two tips 5685.5(1) can be adjusted to vary the force required to assemble to frame and yoke (e.g., if the force for assembly needed to be adjusted downwards, the distance between the tips 5685.5(1) could be increased).

The central hub **5685.1** (e.g., shown in FIGS. **22-4** to **22-6**) is generally circular and may have a hollow core. The central hub **5685.1** locks with the cavity **5636** of the frame connector **5634** (e.g., see FIG. **22-12**). This allows for greater stability when slidingly connected with the frame and also aids disconnection of the interlocking pieces. When the frame connector **5634** engages with the central hub **5685.1**, there is a snapping sound that aims to provide tactile feedback to the user that the parts are assembled correctly. The central hub **5685.1** is connected to the rear wall **5685.3** via an arm **5685.6** (e.g., see FIGS. **22-4**). The posterior side of the arm **5685.6** can have multiple ribs **5685.6(1)** (e.g., 2 or 3 ribs) as shown in FIG. **22-4**, that are elevated from the rear wall **5685.3** by, e.g., 2 mm. Ribs **5685.6(1)** act to guide the frame into the yoke and thus ensure correct assembly of the parts.

The rear wall **5685.3** has a window **5685.7** to allow for unimpeded rotation of the frame with respect to the yoke (e.g., see FIGS. **22-5** and **22-6**). It also enables the patient to visually assess if the assembly is correct. In addition, the window **5685.7** is provided to mold the ratchet teeth.

FIGS. **22-8** to **22-16** illustrate the attachment of the yoke to frame interface **5685** to a respective connector **5634** of the frame **5630**. In FIGS. **22-8** and **22-9**, the frame connector base **5634.1** is inserted past the tips **5685.5(1)** of engagement lip **5685.5** on the yoke to begin alignment. Ribs **5685.6(1)** are also guiding the frame connector **5634** in position on the anterior side of the connector. FIG. **22-9** demonstrates the interaction of the central hub **5685.1** with the anterior surface of the frame connector **5634** when the parts are not fully engaged. The central hub **5685.1** is flexed outwards about arm **5685.6**. FIG. **22-10** is a photograph of this arrangement.

In FIGS. **22-11** and **22-12**, the frame connector base **5634.1** has passed through the tips **5685.5(1)** of engagement lip **5685.5** on the yoke. The central hub **5685.1** has engaged with cavity **5636** and snapped back from its flexed position to its original position (as shown in FIG. **22-12**). This creates a tactile connection that enables patients to hear when the assembly is correctly joined. Once the connector **5634** has slotted into the yoke, the locking bumps **5638** engage with the ratchet teeth **5685.4** (e.g., demonstrated by FIGS. **22-14** and **22-15**). The cavity **5636** of the frame connector **5634** includes a yoke snap clearance **5636.1** that provides sufficient space for the central hub **5685.1** to relax or resiliently recover to its original position. Similar to window **5685.7**, the yoke snap clearance **5636.1** is designed to ensure that there is no impedance on the rotational motion of the yoke to frame interface **5685** (see FIG. **22-12**).

FIGS. **22-13** and **22-16** are photographs that show the fully assembled frame **5630** and yoke **5655**. Also, FIGS. **22-17-1** and **22-17-2** illustrate the frame **5630** being rotated relative to the yoke **5655**.

FIGS. **22-18-1** to **22-18-3** are various views of a mold M for molding the frame **5630** according to an embodiment of the present invention. As illustrated, the mold M may include upper and lower molds UM, LM for molding the main body of the frame **5630** and side molds SM for molding the frame connectors **5634** of the frame **5630**. As illustrated, the frame **5630** may include draft features (angled surfaces) to facilitate removal from the mold M.

FIGS. **22-19-1** to **22-19-7** illustrate the headgear yoke **5655** attached to a headgear strap **5653**, e.g., via stitching, according to an embodiment of the present invention. FIGS. **22-20-1** to **22-20-5** illustrate a fully assembled patient interface **5610** according to an embodiment of the present invention. As illustrated, the patient interface **5610** includes a frame **5630** (as described in reference to FIGS. **22-1-1** to **22-1-8**), a nasal prong assembly **5620** (as described in reference to FIGS. **16-13-1** to **16-13-7**), an elbow **5740**, short tube **5770**, and swivel **5790** (as described in reference to FIGS. **18-8-1** to **18-8-7** and FIGS. **20-5-1** to **20-5-6**), headgear including headgear yoke **5655** and straps **5653** (as described in reference to FIGS. **22-2** to **22-19-7**), and tube retainer **5561** and headgear buckle **5560** (as described in reference to FIGS. **5-42-1** to **5-42-6** and FIGS. **5-43-1** to **5-43-7**).

FIGS. **22-20-6** and **22-20-7** illustrate the rear or back strap **5657** of the patient interface **5610**. As illustrated, the back strap **5657** includes thinner end portions **5657(1)** (e.g., 19 mm width) adapted to engage a respective slotted connector portion of the headgear yoke **5655** and a wider intermediate portion **5657(2)** (e.g., 38 mm width). The wider intermediate portion **5657(2)** includes a slot **5658** which spreads the intermediate portion apart so that it can act like two smaller width straps (e.g., 2×19 mm straps), e.g., slot allows the intermediate portion to conform to the back of the patient's head in use. Stress release holes **5659** are provided on each of the slot **5658**, e.g., so the back strap does not tear. In an embodiment, the slot **5658** is formed by a relatively straight cut between the holes **5659**. Also, the back strap **5657** may be constructed of a Breathoprene headgear material including an un-broken loop (UBL) side **5660(1)** and a Lycra side **5660(2)**.

FIGS. **22-24** and **22-25** illustrate a yoke to frame attachment mechanism according to another embodiment of the present invention. In this embodiment, at least one yoke and optimally both yokes **7255** are engaged with the frame **7230** via a ball and socket joint **7285**.

The ball and socket joint **7285** allows greater axial rotational and some lateral rotation. A high degree of rotation at the yoke to frame interface allows the respiratory mask to better accommodate a larger range of face shapes and sizes. Also, infinite adjustment allows the patient to have a larger range of motion when using the respiratory mask, while maintaining a comfortable and effective seal. The ball and socket joint **7285** is a familiar mechanism and visually simple to assemble so therefore more likely to be utilized effectively by patients.

In the illustrated embodiment, the socket **7210** is provided to the yoke **7255** (e.g., integrally formed in one piece therewith) and the ball **7240** is provided to the frame **7230** (e.g., integrally formed in one piece therewith). However, it should be appreciated that the opposite arrangement is possible, i.e., socket on frame and ball on yoke.

As illustrated, the socket **7210** on yoke **7255** is a cavity with a generally rounded profile. In an embodiment, the socket **7210** is in the shape of a hemisphere. In another embodiment, the socket **7210** is part of a hemisphere. The socket **7210** may have a lip **7215** on its outer edge as shown in FIG. **22-25**, which lip **7215** aids in securely fastening the ball **7240** to the socket **7210**. The lip **7215** also limits the movement of the frame **7230** beyond desirable limits so that the respiratory mask is able to maintain its seal. In an alternative embodiment, the socket **7210** may include a lead-in to facilitate connection of the joint.

In an embodiment, the ball **7240** on frame **7230** may be generally spherical, elliptical, or any other rounded shape. In another embodiment, the ball **7240** may be part of a sphere or any rounded shape, e.g., a hemisphere. In yet another embodiment, the ball **7240** may be hollow or partly hollow.

In the illustrated embodiment, the ball **7240** may be engaged with the socket **7210** by a push fit. In an alternative embodiment, the ball **7240** may be engaged with the socket

7210 by a sliding connection. In an embodiment, the ball 7240 has the same or larger diameter D than that of socket 7210 for an interference fit (e.g., FIG. 22-25 illustrates an embodiment where ball 7240 and socket 7210 have the same diameter D).

In another alternative embodiment, the frame and yoke may be integrally formed in one piece. In an embodiment, the frame and yoke may include different colors or transparencies with respect to one another.

2.4.3 Yoke to Frame Rotation Indicator

In an embodiment, rotation indicators may be provided on the frame and/or yokes to indicate to the user that the frame can rotate relative to the yokes. In addition, the rotation indicators may function as position markings to indicate the frame's position with respect to the yokes, e.g., used as a reference for preferred naso-labial rotation angle.

For example, a series of markings (e.g., dots, arrows, combination of dots/arrows, etc.) may be provided on the frame that align with a position mark (e.g., line, dot, arrow, etc.) provided on the yokes to indicate the frame's position.

In FIGS. **19-21-1** to **19-21-3**, the frame **5030** includes a series of dots **5002** with a center one of the dots (having a larger size) aligned with a horizontal axis of the frame **5030** (e.g., see FIGS. **19-21-3**). In this embodiment, the dots **5002** are provided on only one side of the frame **5030**. The adjacent yoke **5055** includes a line **5004** to align with a selected one of the dots **5002** on the frame **5030**.

In FIGS. **19-22-1** to **19-22-4**, the frame **5030** includes a series of dots **5002** with a center one of the dots (having a larger size) offset from a horizontal axis of the frame (e.g., see FIG. **19-22-4**). In this embodiment, the dots **5002** are provided on both sides of the frame **5030**. The adjacent yoke **5055** includes a line **5004** to align with a selected one of the dots **5002** on the frame **5030**. The intent of off-center dots in FIGS. **19-22-1** to **19-22-4** is that the nominal yoke position is indicated by the large, center one of the dots.

In FIGS. **19-23-1** to **19-23-4**, the frame **5030** includes a dot **5002**(**1**) aligned with a horizontal axis of the frame (e.g., see FIG. **19-23-4**) and arrows **5002**(**2**) provided on each side of the dot **5002**(**1**). In this embodiment, the dot/arrows are provided on only one side of the frame **5030**. The adjacent yoke **5055** includes an arrow **5004** to align with a selected dot/arrow on the frame **5030**.

In each embodiment, the markings on the frame and yoke may be printed, molded, etched, polished, etc. Also, the markings on the frame and/or yoke may include other configurations (e.g., color-coded, numbered, varying sizes, bands with ascending heights, etc.). Markings may be provided on one or both sides of the frame, and markings may be provided on one or both of the yokes. In addition, any suitable number of markings may be provided on the frame and yoke, and the markings may have any suitable spacing.

2.4.4 Yoke to Nasal Prong Assembly Rotation Indicator

In an embodiment, rotation indicators may be provided on the nasal prong assembly and/or yokes to indicate to the user that the nasal prong assembly/frame can rotate relative to the yokes. In addition, the rotation indicators may function as position markings to indicate the nasal prong assembly's position with respect to the yokes, e.g., used as a reference for preferred naso-labial rotation angle.

For example, a series of markings (e.g., dots, arrows, combination of dots/arrows, etc.) may be provided on the nasal prong assembly that align with a position mark (e.g., line, dot, arrow, etc.) provided on the yokes to indicate the nasal prong assembly's position.

As best shown in FIGS. **16-15-4** to **16-15-6**, the gusset **6022** of the nasal prong assembly **6020** includes a series of dots **6025**, e.g., 2, 3, 4 or more dots. The dots may vary in size, e.g., a center one of the dots (having a larger size) aligned with a horizontal axis of the nasal prong assembly. In this embodiment, the dots **6025** are provided on only one side of the nasal prong assembly **6020**. As best shown in FIG. **22-23-7**, the adjacent yoke **6555** includes a protrusion or dot **6504** (may also be in the form of a line or other suitable alignment indicator) to align with a selected one of the dots **6025** on the cushion **6020**.

Similar to the concepts shown in FIGS. **19-21-1** to **19-23-3**, the dots **6025** featured on the nasal prong assembly **6020** can align with the dot **6504** on yoke **6555** to indicate the position of the nasal prong assembly with respect to the yoke. This re-positions the patient interface so that it can have the same settings each time. In an embodiment, the alignment dot or marker on the yoke may be positioned at any suitable location along the arm of the yoke, e.g., closer to the yoke's interface with the frame. Also, in an embodiment, as the yoke is rotated relative to the nasal prong assembly, the yoke may cover one or more of the dots **6025** (i.e., instead of alignment markers on the nasal prong assembly and yoke meeting, one may adjust the system until a certain number of dots are visible, e.g., only 1 or 2 alignment dots are visible).

Another advantage of this alignment concept is it indicates to the user that the nasal prong assembly should be positioned in the frame in such a way that the adjacent yoke **6555** with dot **6504** is aligned with dots **6025**. This therefore indicates that the nasal prong assembly will be oriented so that it interfaces with the nares of the patient correctly, i.e., nasal prong assembly placed in the frame in the right direction. For example, if the patient interface was completely disassembled, it is obvious that the headgear straps are to be placed along the side of the face with the yokes facing outwards. The user would then proceed to connect the frame to the yokes (which can be put in either way and still work). The alignment dots on the nasal prong assembly can then be positioned so that they are on the side of the yoke with the alignment dot. This means the nasal prong assembly is in the right direction, i.e., with the largest side of the gusset touching the face of the user and the company logo facing outwards. Should the user attempt to align the nasal prong assembly in such a way that the alignment dots on the nasal prong assembly are over the yoke that does not have an alignment dot, the nasal prong assembly will be facing the wrong way, i.e., company logo touching the face of the user.

In each embodiment, the markings on the nasal prong assembly and yoke may be printed, molded, etched, polished, etc. Also, the markings on the nasal prong assembly and/or yoke may include other configurations (e.g., color-coded, numbered, varying sizes, bands with ascending heights, etc.). Markings may be provided on one or both sides of the nasal prong assembly, and markings may be provided on one or both of the yokes. In addition, any suitable number of markings may be provided on the nasal prong assembly and yoke, and the markings may have any suitable spacing.

First End Portion, First Embodiment

FIGS. **6-1** to **6-4** illustrate an embodiment of headgear yoke **55**. As illustrated, the first end portion **55**(**1**) includes a yoke ring **56** (also referred to as a retaining member or connector) that is adapted to engage a respective end or connector portion of the frame of the nasal prong assembly **20** (e.g., see FIGS. **2-1** and **2-2**). In addition, a seal ring or seal portion **58** (see FIG. **1-1**) is provided to the yoke ring **56** and is adapted to sealingly engage a plug or elbow.

Further details of such yoke ring **56** and seal ring **58** (and attachment to a plug or elbow) are described in U.S. Patent Application Publication Nos. 2004-0226566, 2006-0137690, and 2005-0241644, each of which are incorporate herein by reference in its entirety.

First End Portion Alternative Embodiment

In the embodiment of headgear yoke **5055** shown in FIGS. **19-1** to **19-5**, the first end portion **5055(1)** includes a support arm **5080**, a yoke to frame interface **5085** provided to an end of the support arm **5080** and adapted to engage a respective connector **5034** of the frame **5030**, and a cheek support **5084** (also referred to as a stability arm).

Second End Portion, First Embodiment

As shown in FIGS. **1-1**, **6-1** to **6-2**, and **6-5** for the embodiment of headgear yoke **55**, the second end portion **55(2)** provides a slotted connector portion including a slot **65** that defines a cross-bar **66** that is adapted to engage a respective end of the rear strap **57**. Specifically, a respective end **57(1)** of the rear strap **57** may be wrapped around the cross-bar **66** of the yoke, in a known manner. The free end of the rear strap **57** may be tapered (e.g., to aid threading through the slot **65**) and secured to the remainder of the strap by a hook and look arrangement, e.g., Velcro®.

The use of Velcro attachment at the headgear yokes eliminates the use of a rear buckle to adjust the rear strap **57**. This arrangement improves comfort by removing discomfort and irritation caused by the patient lying on a rear buckle in use.

Second End Portion Alternative Embodiment

As shown in FIGS. **13-1** to **13-4** and **19-1** to **19-4** for the embodiment of headgear yoke **5055**, the second end portion **5055(2)** provides a slotted connector portion including a slot **5065** that defines a cross-bar **5066** that is adapted to engage a respective end of the rear strap **5057**. Specifically, a respective end **5057(1)** of the rear strap **5057** may be wrapped around the cross-bar **5066** of the yoke, in a known manner. The free end of the rear strap **5057** may be tapered and/or locally thinned (e.g., to aid threading through the slot **5065**) and secured to the remainder of the strap by a hook and look arrangement, e.g., Velcro®.

In an embodiment, the slot may have a width of about 3-5 mm, e.g., 4 mm, and a length of about 15-25 mm, e.g., 21 mm. However, these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application.

Adjustment of Strap Length

Headgear Buckle

As shown in FIG. **1-1**, the headgear buckle **60** is adapted to be centrally located on the patient's head to allow symmetrical adjustment of the headgear **50**, e.g., adjustment of strap tension can be accomplished by pulling loose tabs on the top of the patient's head in opposite directions. Specifically, the headgear buckle **60** includes a first locking portion **60(1)** and a second locking portion **60(2)**. The first locking portion **60(1)** is adapted to be removably and adjustably coupled with one of the upper strap portions **53(1)** and the second locking portion **60(2)** is adapted to be removably and adjustably coupled with the other of the upper strap portions **53(1)**. Each of the upper strap portions **53(1)** may be wrapped around the cross-bar of the associated locking portion of the buckle, in a known manner. The free ends of the upper strap portions **53(1)** may be tapered (e.g., to aid threading through respective locking portions) and secured to the remainder of the strap by a hook and look arrangement, e.g., Velcro®.

The headgear buckle **60** joins the headgear straps and yokes to form the headgear, allows fine and infinite adjustments of the headgear straps, allows quick and easy adjustments and loosening of the headgear straps, and/or allows the straps to pull symmetrically against the head to minimize dislodgement of the nasal prong assembly during adjustment.

As noted above, the rear strap eliminates the use of a rear buckle and uses Velcro fasteners, e.g., to improve comfort. Alternative embodiments to eliminate or reduce discomfort that may be caused by a headgear buckle include: using an isolated highly elastic section that allows the user to easily stretch the headgear over the head to remove/replace it; reducing the overall height of the buckle (e.g., low profile buckle); adding padding to the buckle; allowing the user to customize the position of the buckle so that it can be located on an area of the head that will not cause irritation to the user (e.g., positioned along side regions of the head rather than at the back); and/or introducing a textile buckle that provides the same function as a plastic buckle; introducing a headgear material that provides the same function as a buckle.

Soft and Flexible Link

In an alternative embodiment, the headgear buckle may be in the form of a soft and flexible link (also referred to as a linking element, link element or link member). Such a link is disclosed in Australian Provisional Application No. AU 2008900891, filed Feb. 25, 2008, which is incorporated herein by reference in its entirety. The link provides a more comfortable linking element for headgear straps and has sufficient strength in tension to secure a mask to a patient's face under pressure.

FIGS. **5-44-1** to **5-44-5** are respectively side, top, longitudinal cross-section, bottom, and isometric views of a link **6134** according to an embodiment of the invention.

In an embodiment of the link (see FIGS. **5-44-1** to **5-44-5**), D**1** may be about 0.5-1.5 mm, e.g., 1.0 mm, D**2** may be about 1-3 mm, e.g., 2.0 mm, D**3** may be about 45-50 mm, e.g., 48 mm, D**4** may be about 15-25 mm, e.g., 19 mm, D**5** may be about 20-25 mm, e.g., 23.0 mm, D**6** may be about 2-4 mm, e.g., 3.0 mm, D**7** may be about 17-22 mm, e.g., 19.5 mm, and D**8** may be about 2-4 mm, e.g., 3.0 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

The illustrated link **6134** is formed of a relatively soft and flexible material, preferably an elastomer, e.g., thermoplastic elastomer (TPE), and more preferably a thermoplastic polyester elastomer such as Hytrel™ by DuPont Corporation. Alternatively, the link may be constructed from a nylon or other material with sufficient strength and flexibility. The link may be made by any suitable method, for example by molding.

The illustrated link **6134** may be elongate in the dimension which is adapted to lie parallel to the strap length, and may be approximately elliptical in plan view as illustrated (see FIG. **5-44-2**).

The link is thin (e.g., less than about 3 mm, and more preferably about 0.75 to 2.5 mm thick) in its smallest transverse dimension, and mostly generally planar in its unflexed state. Preferably, the link is symmetrical both end-to-end and about a central longitudinal plane, to facilitate assembly and reassembly of the headgear without needing to have regard to the orientation of the link. In an embodiment, the link has a thickness less than the strap thickness.

The link **6134** has opposed end portions **6136**, a pair of transverse strap-receiving slots **6140** and a central portion **6142** between and adjacent the slots. By including a pair of slots **6140** rather than a single slot, the headgear straps are less prone to skewing in use.

The link of FIGS. **5-44-1** to **5-44-5** is adapted to cooperate with a fabric and foam headgear strap of approximate width 19 mm and approximate thickness 2.7 mm. The illustrated link is approximately 48 mm long by 23 mm wide by 1 mm to 2 mm thick. The edges of the link may be rounded.

In the illustrated embodiment, the end portions **6136** (which correspond substantially with that part of the link which is overlaid by the strap in use) are approximately 1 mm thick.

The illustrated link further includes a pair of parallel 19 mm by 3 mm transverse slots **6140** spaced apart by about 3 mm, and a reinforced central portion **6142** adjacent the slots.

It should be appreciated that the link may be adapted for use with headgear straps of other suitable length, width, and thickness, e.g., size of slots in link may be sized accordingly to accommodate any suitable size headgear strap.

In the illustrated embodiment, the central portion **6142** is strengthened by being thickened relative to the end portions **6136**. The reinforced central portion **6142** may comprise an I-shaped thicker region of 2 mm thickness. The center bar **6144** of the I-shape is located between the two slots and the cross bars **6146** of the I-shape are located between the ends of the slots **6140** and the side edge of the link, and taper down in thickness towards their ends.

It will be appreciated that the central portion **6142** may strengthened in ways other than by increased thickness, for example by co-molding with different materials, or attachment or inclusion of reinforcing members.

The thickest portion of the link and straps in use is a double thickness of strap together with a thickness of the end portions **6136**. By providing a reinforced, thickened central portion **6142**, the linking element is strengthened without contributing to the overall thickness of the assembly of straps and link, since the straps do not wrap around the central portion in use. See FIG. **5-45**.

FIG. **5-45** is a schematic section of the link **6134** (similar to FIG. **5-44-3**), showing the location of the rear strap portions **6130***a*, **6130***b* when connected to the link.

As can be seen in FIG. **5-45**, the slots **6140** in the link are sized to allow threading of the straps therethrough by the user to adjust the headgear fit and tension, with the strap ends being doubled back onto themselves and secured, for example by the use of a hook material **6148** (e.g., Velcro™ or similar) stitched or otherwise attached to the end portion of the strap. The strap surface facing the hook tape may have a complementary loop material attached, or alternatively the hook tape may be secured against the outer fabric layer of the strap itself.

The link **6134** and strap **6130** are thus adapted to connect together by the strap making a single pass through the link and forming a U-shape with both legs of the U parallel to the adjacent surface of the patient's head.

The thicker portion **6144** of the link **6134** preferably has a thickness of less than two strap thicknesses, and does not protrude beyond the combined thickness of the doubled-over strap connected to the link.

In this arrangement, the overall thickness of the strap arrangement is approximately a double thickness of strap. This contrasts with prior art arrangements where more than a double thickness of strap is located on the head, for example using a ladder lock, leading to an uncomfortable bulk to lie on. See FIG. **5-46**, which shows one end of a prior art ladder lock-type headgear buckle **6200** and strap **6202**. Tests have shown that the pressure on a typical head are approximately halved from about 13 g/mm^2 to about 6 g/mm^2 when using a link according to an embodiment of the present invention.

In accordance with a preferred form of the present invention, a length of hook & loop material (e.g., Velcro™) is used to secure an end of a strap to itself and to retain the strap in tension.

The rounded corners of the linking element (see for example FIG. **5-44-2** and **5-44-4**) reduce the likelihood of a sharp corner impinging on the patient's head, and lead to improved comfort.

The illustrated arrangement is intended to allow a lower link profile and provide increased comfort to the patient, while retaining the ease of adjustment of current link member designs.

While the illustrated embodiment of the invention is a flexible linking element, other forms may be more rigid, or completely rigid.

Such flexible linking element may be used to removably and adjustably couple upper or top strap portions of headgear (e.g., similar to buckle **60** in FIG. **1-1**). Also, such flexible linking element may be used to removably and adjustably couple rear strap portions of headgear (e.g., see FIGS. **22-23-1** to **22-23-6** described below).

2.5 Side & Rear Stabilising Portions

2.5.1 Headgear

2.5.1.1 Introduction

A mask assembly in accordance with an embodiment of the invention provides stability to the interface through a combination of components referred to as "headgear". The headgear may be broadly described as comprising a pair of side portions including cheek & upper/crown portions and a rear portion. In the preferred embodiment, the cheek portions include stabilizing features or "yokes". Furthermore, as discussed above naso-labial angular adjustment is provided via a yoke to frame connection mechanism.

As shown in FIG. **1-1**, the headgear **50** includes two side portions **52** with a rear portion **54** connecting the side portions **52**. Each side portion **52** includes a side strap **53** (e.g., constructed of Breathoprene) and a headgear yoke **55** (e.g., constructed of a molded plastic such as nylon) attached to the side strap **53**. The headgear yoke **55** (also referred to as a rigidizer, rigidizing element, stabilizer, stabilizing element, stiffened headgear element) acts as a stiffener or rigidizer to add rigidity to the headgear and add stability to the sides. The rear portion **54** includes a rear strap **57** (e.g., constructed of Breathoprene) that passes around a rear portion of the patient's head (e.g., below the occiput).

Each side strap **53** includes an upper strap portion **53**(**1**) that passes over the top of the patient's head. The upper strap portions **53**(**1**) of the side straps **53** are coupled to one another by a headgear buckle **60**. The rear strap **57** includes end portions **57**(**1**) coupled to respective headgear yoke **55**.

The upper strap portions **53**(**1**) are structured to adjust the sealing force because they pull the nasal prong assembly **20** up into the patient's nose. The rear strap **57** is structured to adjust the stability of the nasal prong assembly **20** because it pulls the nasal prong assembly **20** back into the patient's face on the top lip of the patient.

The headgear **50** captures the crown of the patient's head (when assembled) while avoiding the base of the neck, accommodates a sufficient range of adjustment to cover a broad range of the target population, and/or provides sufficient flexibility for removal of the interface without requiring readjustment. In an embodiment, the headgear **50** may be provided in multiple sizes (e.g., small, medium, large).

In another embodiment as shown in FIGS. **13-1** to **13-4**, the headgear **5050** includes two side portions **5052** with a rear portion **5054** connecting the side portions **5052**. The headgear **5050** is structured to stabilize the patient interface on the patient's head and apply sufficient force for sealing. In addition, the headgear is structured to provide one or more of the functions described below, e.g., unobtrusive, comfortable, easy to use, etc.

Each side portion **5052** includes a side strap **5053** (e.g., constructed of Breathoprene) and a headgear yoke **5055** (e.g., constructed of hard plastic such as Nylon, Hytrel) attached to the side strap **5053**. The headgear yoke **5055** (also referred to as a rigidizer, rigidizing element, stabilizer, stabilizing element, stiffener, stiffened headgear element) acts as a stiffener or rigidizer to add rigidity to the headgear and add stability to the sides. The rear portion **5054** includes a rear strap **5057** (e.g., constructed of Breathoprene) that passes around a rear portion of the patient's head (e.g., below the occiput).

Each side strap **5053** includes an upper strap portion **5053(1)** that passes over the top of the patient's head. The upper strap portions **5053(1)** of the side straps **5053** are coupled to one another by a headgear buckle **5060** (e.g., constructed of hard plastic such as Nylon, Hytrel). The rear strap **5057** includes end portions **5057(1)** coupled to respective headgear yoke **5055**.

FIGS. **22-21-1** to **22-23-6** illustrate headgear according to another embodiment of the present invention. In this embodiment, a rear strap portion is incorporated into each side strap.

Specifically, FIGS. **22-21-1** to **22-21-8** shows a left-hand-side (LHS) side strap **6553**L with headgear yoke **6555**L and FIGS. **22-22-1** to **22-22-8** shows a right-hand-side (RHS) side strap **6553**R with headgear yoke **6555**R. Each of the side straps **6553**L, **6553**R includes an upper strap portion **6553(1)** adapted to pass over the top of the patient's head, a front strap portion **6553(2)** adapted to pass along the side of the patient's head, and a rear strap portion **6553(3)** adapted to pass around a rear portion of the patient's head. As illustrated, each side strap **6553**L, **6553**R has a general Y-shape configuration, e.g., similar to headgear in ResMed's Swift II mask.

FIG. **13-5** is a schematic view illustrating headgear vectors according to an embodiment of the present invention (e.g., in relation to FIGS. **13-1** to **13-4** but also applicable to FIGS. **22-21-1** to **22-21-8** for example). In an embodiment, **A1** is about 152°, **A2** is about 124°, and **A3** is about 84°. However, other dimensions are possible, e.g., depending on application. Such headgear vectors provide stability to the nasal prongs in order to maintain seal and provide sufficient ear clearance for comfort.

The headgear yoke **6555**L, **6555**R is substantially similar to the headgear yoke **5655** described above (e.g., see FIGS. **22-7-1** to **27-7-8**). In contrast, the stitching groove **6559** of the headgear yoke **6555**L, **6555**R loops around the edge of the second end portion **6555(2)** thereof.

In the illustrated embodiment, the upper strap portion **6553(1)** and the front strap portion **6553(2)** are formed in one piece, and the rear strap portion **6553(3)** is attached to the upper and front strap portions by stitching (e.g., stitch joint indicated at **6556**). However, the rear strap portion **6553(3)** may be provided to the upper and front strap portions in other suitable manners, e.g., formed in one piece therewith, attached via adhesive, attached via mechanical connector, etc.

As illustrated, the free end of each rear strap portion **6553(3)** includes a Velcro® fastener or tab of hook material **6557**. In addition, one side of each rear strap portion **6553(3)** is coated with un-broken loop (UBL) material **6558** (e.g., instead of lycra) which allows the tab of hook material **6557** to fasten anywhere along its length. The tab of hook material **6557** provides an "easy peel" arrangement wherein only a portion of the tab of hook material **6557** engages with the UBL material **6558** making it easier to grip.

FIGS. **22-22-9** and **22-22-10** illustrate under-side and top-side views of the tab of hook material **6557**. The under-side view of FIG. **22-22-9** shows the UBL side **6558** of the Breathoprene headgear material, Velcro hooks **6557(1)** of the hook material, and an area **6557(2)** with the hooks **6557(1)** removed, e.g., to facilitate gripping or peeling the tab. The hooks may be removed in area **6557(2)** through shaving off, ultrasonic removal, or other suitable removal means. The top-side view of FIG. **22-22-10** shows the Lycra side **6560** of the Breathoprene headgear material (opposite side of UBL) and the attachment area **6557(3)** of the tab to the Lycra side **6560**. In an embodiment, the tab may be ultrasonically welded to the Lycra side **6560**.

In use, the upper strap portions **6553(1)** of the side straps **6553**L, **6553**R may coupled to one another by a top headgear buckle or link, and the rear strap portions **6553(3)** of the side straps **6553**L, **6553**R may be coupled to one another by a rear headgear buckle or link.

For example, FIGS. **22-23-1** to **22-23-6** illustrate a fully assembled patient interface **6510** with the upper strap portions **6553(1)** coupled by tube retainer **5561** and headgear buckle **5560** (as described in reference to FIGS. **5-42-1** to **5-42-6** and FIGS. **5-43-1** to **5-43-7**) and the rear strap portions **6553(3)** coupled by linking member **6134** (as described above in reference to FIGS. **5-44-1** to **5-45**). In addition, the patient interface **6510** includes a frame **6030** and nasal prong assembly **6020** (as described in reference to FIGS. **16-14-1** to **16-16-8**).

In the illustrated embodiment, the headgear yoke is formed separately from the frame and attached thereto. In an alternative embodiment, the headgear yoke may be integrally formed with the frame so that the frame and headgear yoke provide a one-piece structure.

The headgear may provide one or more of the following functions: support and stabilize the nasal prong assembly on the user in a manner that maintains the integrity of the nasal prong seal around the naris region during the delivery of pressurized air; allow the user to adjust and set the nasal prong to a desired position to obtain and maintain an "exact fit" with a good nasal prong seal around the naris region during the delivery of pressurized air; accommodate an anthropometrically diverse range of users (e.g., 95% of male and female population); accommodate a range of different sleeping positions and transitions in sleeping positions including the ability to support different tube mounting configurations (e.g., allow patient to sleep on side without the barrel-like base and/or prongs being dislodged); allow the user to remove and replace the interface without significant loosening of the adjustment mechanisms; ergonomically comfortable and not a source of marking or irritation to the user; unobtrusive and both visually and physically minimal avoiding the user feeling stifled or claustrophobic; allow the user to wear glasses with the interface; aesthetically pleasing, high quality and stylish; provide a region, or regions, for the application of branding; allow user to easily assemble/disassemble from the nasal prong assembly; and/or allow user to easily fit and remove from head.

2.5.1.2 Headgear Strap Material

In the illustrated embodiment, each of the headgear straps may be constructed of Breathoprene including an open cell polyurethane laminated between Lycra outer layers. In alternative embodiments, the nap of the outer layer material may be altered, the density of the core material may be altered, and/or the color of the individual materials may be altered.

For example, each of the straps may be constructed of micro-fiber nylon (e.g., Tattel), which may provide a relatively soft edge and feel.

However, other suitable materials are possible. In an embodiment, the straps have a material thickness of about 2-3 mm, e.g., 2.5 mm.

In another embodiment, the straps may be constructed of a more elastic headgear material to increase decoupling of headgear forces such that shifts in the headgear position does not significantly influence the seal region.

FIG. **30** is a cross-section of Breathoprene material according to an embodiment of the present invention. As illustrated, the material includes a layer L**1** of Nylon/Spandex Loop, a layer L**2** of Open-cell Polyurethane, and a layer L**3** of Polyester/Lycra jersey. The material has the benefits of being soft, light, flexible and comfortable. Moisture is allowed to escape through the material from the skin, and air is allowed through to maximize heat dispersion and breath-ability, making the headgear more comfortable to wear for longer periods.

2.5.1.3 Headgear Strap Dimensions and Angles

In an embodiment, an intermediate strap portion **5053**(**2**) of each side strap **5053** (e.g., see FIG. **13-2**) has a width of about 17-21 mm, e.g., 19 mm, and an upper strap portion **5053**(**1**) of each side strap **5053** (e.g., see FIG. **13-4**) has a width of about 17-21 mm, e.g., 19.8 mm. Also, the rear strap **5057** may include a central portion with an increased width such that the end portions **5057**(**1**) of the rear strap **5057** (e.g., see FIG. **13-3**) have a width of about 17-21 mm, e.g., 19 mm, and the central portion **5057**(**2**) of the rear strap **5057** (e.g., see FIG. **13-3**) has a width of about 36-40 mm, e.g., 38 mm. The wider, central portion **5057**(**2**) is adapted to sit further down the back of the patient's head.

As best shown in FIGS. **13-1** and **13-4**, the upper strap portion **5053**(**1**) of each side strap **5053** is sufficiently long so that the largest patient can be fitted to the headgear, which results in the upper strap portion **5053**(**1**) overhanging at least a portion of the yoke **5055** when fitted to a smaller person. In an exemplary embodiment, the strap length of the upper strap portion **5053**(**1**) (measured from the top of the yoke) may be about 180-230 mm, e.g., 193 mm.

As best shown in FIG. **13-3**, the end portions **5057**(**1**) of the rear strap **5057** are sufficiently long so that the largest patient can be fitted to the headgear, which results in overhang of the end portions **5057**(**1**) when fitted to a smaller person. In addition, a gap may be provided between the free ends of the end portions **5057**(**1**). In an exemplary embodiment, the strap length of the rear strap **5057** may be about 530-560 mm, e.g., 545 mm.

Velcro Tab

As shown in FIGS. **21-1** and **21-2**, a Velcro tab **5059** (hook material) is provided to the end of each rear strap end portion **5057**(**1**) (see FIGS. **13-1** to **13-4**) to secure the strap in position. Such Velcro arrangement improves comfort and usability (locating, pealing, and reattaching). In addition, such Velcro arrangement is not visible when the Velcro is attached onto the back strap. In an embodiment, the Velcro provides an effective engagement area of about 300-500 mm^2, e.g., 375 mm**2**. In an embodiment, the rear strap end portion and Velcro tab may have a tapered or triangular shape. In such embodiment, the rear strap may be wider at the yoke connection, e.g., for stiffness and minimal vertical movement. The central portion **5057**(**2**) may have a reduced thickness with respect to the remainder of the rear strap, e.g., for increasing pressure for better grip.

In an embodiment, the Velcro tab **5059** may be ultrasonically welded to the rear strap. For example, the Velcro tab **5059** may be ultrasonically welded in two locations (see FIG. **21-1**) or the Velcro tab **5059** may be ultrasonically welded in an enclosed pattern (see FIG. **21-2**). However, other suitable attachment methods are possible.

2.5.2 Stabilising Element (Yoke)

Each headgear yoke **55** is constructed from a rigid or semi-rigid material (e.g., injection molded from nylon, polypropylene, polycarbonate, etc.) and attached to a respective side strap **53**. The yokes **55** retain at least a partial portion of the basic shape of the headgear **50**, which may facilitate donning of the headgear **50**.

As shown in FIGS. **1-1** and **6-1** to **6-5**, each yoke **55** includes a first end portion **55**(**1**) adapted to secure a respective end of the nasal prong assembly **20** in an operative position, a second end portion **55**(**2**) adapted to engage a respective end of the rear strap **57**, and an intermediate portion **55(3)** between the first and second end portions **55**(**1**), **55**(**2**) adapted to add rigidity to a respective side strap **53**.

The headgear yokes **55** provide rigidity for stabilizing the interface and flexibility for comfort (when assembled), provide a flexible stiffening section for the headgear straps, form a retaining interface with the first end portion (yoke ring), and/or provide alignment markers to correspond to the correct front-to-back orientation of the nasal prong assembly.

Yoke to Strap Attachment

Each yoke **55** may be attached to a respective side strap **53**, e.g., via stitching, welding, gluing, or otherwise mechanically affixed.

In an embodiment, each yoke **55** may be attached to a respective strap **53** with glue, e.g., Loctite (e.g. 4011 medical grade). In such arrangement, the glue may be provided along a glue path that is spaced inwardly from the side edges of the strap **53** (e.g., 1-5 mm).

In other embodiments, each yoke **55** may be attached to a respective strap **53** with double-sided tape, hot melt glue, and/or the application of heat (non glue).

In another embodiment, a sleeve may be created in the side strap **53**, and the yoke **55** may be inserted into such sleeve.

In yet another embodiment, a yoke or rigidizing section may be provided to a respective strap by a manufacturing process. For example, a thermoforming process may be used to form a one-piece strap with a rigidizing section. In such embodiment, a relatively thick strap may be provided, and then pressure and/or heat may be applied to the strap in certain sections to add the desired rigidity. In an embodiment, the strap may be constructed of a foam material that would allow features to be created in the foam during manufacturing, e.g., seal ring, branding, etc.

In a further illustrated embodiment, each yoke **5055** is attached to a respective side strap **5053** via stitching. As shown in FIGS. **13-1** to **13-4** and **19-2**, a stitching groove **5058** is provided along a length of the yoke **5055** to receive the stitching. As illustrated, the stitching groove **5058** is provided along an intermediate portion of the yoke **5055** (e.g., spaced inwardly from the edges).

The stitching groove **5058** locates the stitching making it flush with the top surface of the yoke, improves aesthetics by providing an overall cleaner appearance, provides a single stitching line to improve comfort levels through reducing edge stiffness of the headgear strap edge (e.g., potentially reducing facial marks), and provides path having sufficient level of attachment and stability. Also, the recessed structure of the stitching groove **5058** provides a thinner yoke wall section (e.g., see FIG. **19-20**) for the stitching needle to punch through, which provides reduced part deformation.

FIG. **19-19** illustrates exemplary dimensions for an embodiment of the stitching groove **5058**. As illustrated, D**1** may be about 1-2 mm, e.g., 1.5 mm, D**2** may be about 0.25-0.75 mm, e.g., 0.4 mm, D**3** may be about 1-2 mm, e.g., 1.2 mm, and D**4** may be about 25-75°, e.g., 45°. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

It should be appreciated that each yoke **5055** may be attached to a respective side strap **5053** in other suitable manners, e.g., via welding, gluing, or otherwise mechanically affixed.

Yoke Width

In the illustrated embodiment, the yoke **55** includes a width that is less than a width of the respective side strap **53**, e.g., intermediate portion **55**(**3**) narrower than side strap **53**.

If stitching is not used to attach the yoke **55** to the respective strap **53** (e.g., yoke attached via welding or gluing), the intermediate portion **55**(**3**) may be even narrower.

However, in an alternative embodiment, the intermediate portion **55**(**3**) may have a width that is substantially the same as the respective strap **53**.

In alternative embodiments, the width of the yoke may be tapered or contoured along its length. For example, FIG. **8-1** illustrates yoke **255** that tapers from a smaller width w to a larger width W. FIG. **8-2** illustrates yoke **355** that has a convex edge **359** along its length, and FIG. **8-3** illustrates yoke **455** that has a concave edge **459** along its length.

In yet another embodiment, as shown in FIG. **8-4**, one or more slots **561** may be provided along a portion of a yoke **555** (e.g., along inner radius of curved portion of the yoke) to reduce the springboard effect provided by the yoke in use.

In a further illustrated embodiment, the yoke **5055** includes a width (e.g., about 9 mm) that is less than a width of the respective side strap **5053** (e.g., about 19 mm), e.g., intermediate portion **5055**(**3**) narrower than side strap **5053**. As described above, such arrangement may eliminate or reduce facial marks in use.

For example, FIG. **19-20** illustrates yoke **5055** attached to strap **5053** by a single stitch **5056**. In an embodiment, the cantilever distance D**1** is about 8.5-10.5, e.g., 9.5 mm.

Materials and Properties of stabiliser/Yoke

First Forms

As noted above, each headgear yoke **55** is constructed from a rigid or semi-rigid material, e.g., nylon, polypropylene, polycarbonate.

In an embodiment, the yoke **55** is sufficiently soft and flexible so that it can bend or conform to suit the patient's head, and sufficiently rigid to efficiently transfer headgear forces/vectors for locating the nasal prong assembly **20** on the patient's face.

In another embodiment, the yoke **55** may be rubber like, e.g., constructed from Santoprene silicon material or thermoplastic. In another embodiment, silicon may be overmolded onto the yokes.

In yet another embodiment, headgear straps may not be provided along the yokes **55**, e.g., straps only provided to cup the patient's head. Alternatively, yokes may not be provided.

In yet another embodiment, a flexible connection between the yoke and frame may be provided by an extension of the silicone seal rings, e.g., to increase decoupling of headgear forces.

In yet another embodiment, a metal component may be inserted in headgear straps around the yoke region to provide stiffness and to allow the user to customize the headgear region to the shape of the patient's face, e.g., in-molded stainless steel wire. In other forms this insert may be constructed from a malleable plastic or TPE.

Alternative Forms—Thermoformed Foam Yoke

FIGS. **12-12-1** to **12-13** illustrate headgear with thermoformed foam yoke.

In FIG. **12-12-1**, the headgear includes headgear straps **3153** that cup the patient's occiput and yoke **3155** to couple the headgear straps **3153** with the nasal prong assembly. The yoke **3155** is constructed of a thermoformed foam material. Also, a molded plastic seal ring **3156** is provided to a proximal end of the yoke **3155**, and a molded plastic buckle **3160** is provided to a distal end of the yoke **3155** to provide lateral adjustment with the headgear straps **3153** (see FIG. **12-12-2**).

In an embodiment, the seal ring **3156** and buckle **3160** may be provided to the yoke **3155** via a thermoformed foam sandwich. For example, FIGS. **12-12-3** and **12-12-4** illustrate a thermoforming process for coupling the molded plastic sealing ring **3156** or buckle **3160** to the foam yoke **3155** with heat/pressure. As shown in FIG. **12-12-3**, a separately molded relative hard plastic part (e.g., seal ring **3156** or buckle **3160**) is positioned between two pieces of foam **3155**(**1**), **3155**(**2**), and the plastic ring **3156** or buckle **3160** and foam pieces **3155**(**1**), **3155**(**2**) are positioned in a molding tool having a top tool half T**1** and a bottom tool half T**2**. The molding tool is heated up and top and bottom tool halves T**1**, T**2** compress the foam pieces **3155**(**1**), **3155**(**2**) and plastic ring **3156** or buckle **3160** so that the foam pieces **3155**(**1**), **3155**(**2**) bond to one another and retain the plastic ring **3156** or buckle **3160** therebetween (see FIG. **12-12-4**). In another embodiment, the seal ring may be integrated to the yoke.

This embodiment provides increased levels of usability (e.g., particularly during fitting and adjustment) for intuitive features such as single piece 3D shaped headgear and lateral headgear tension adjustments.

Also, this embodiment provides an increased level of aesthetics as it utilizes a thermoformed foam section, which provides broad opportunities for aesthetic styling. In FIG. **12-13**, the headgear includes a thermoformed foam yoke **3255** with a thin breathoprene layer attached thereto (e.g., along surface adapted to engage the patient's head in use) for comfort. Similar to **12-12-1**, this embodiment provides increased levels of usability (e.g., particularly during fitting and adjustment) for intuitive features such as single piece 3D shaped headgear and lateral headgear tension adjustments.

Branding

Branding may be molded and/or printed onto the yokes **55**, and such branding may also function as an aid for correct alignment during assembly. The branding may include changes in color/tone.

Alternative Headgear Yoke

FIGS. **12-1** to **12-4** illustrate alternative arrangements of headgear yoke. Each embodiment may include one or more of the following features: localized thinning to adjust flexibility of the yoke, improved comfort, seal ring co-molded to yoke, improved aesthetics, branding (e.g., to show which side is inside/outside for assembly), and/or structured to fit more people.

In FIG. **12-1**, the yoke **2055** has a streamlined arrangement in which the yoke **2055** includes localized thinning or tapers along its length, e.g., inner edge of the yoke tapers towards its distal end, to improve flexibility.

FIG. **12-2** illustrates another embodiment of a yoke **2155** having a streamlined arrangement in which the yoke **2155** includes localized thinning or tapers along its length, e.g., inner edge of the yoke tapers towards its distal end, to improve flexibility. In this embodiment, the yoke **2155** has a smaller width than that shown in FIG. **12-1**.

In FIG. **12-3**, the yoke **2255** has a geometric or symmetric arrangement in which the yoke **2255** has a substantially uniform thickness and shape along its length. In addition, the distal end of the yoke **2255** includes a section **2280** for branding, e.g., section includes branding cut-out.

In FIG. **12-4**, the yoke **2355** has a contoured inner radius or surface and the distal end of the yoke **2355** includes a section **2380** for branding, e.g., bird logo for aesthetic cues. In an embodiment, a soft elastomeric material **2382**, e.g., santoprene, may be co-molded to the yoke **2355** along the contoured surface. In addition, the branding may include a different surface finish than that of the yoke **2355**, e.g., elastomeric surface. The embodiment of FIG. **12-4** provides an increased level of aesthetics as it utilizes branding as an aesthetic cue for the design of the yokes.

Flexible Yoke/Incorporated Seal Ring

FIGS. **12-8** to **12-11-2** illustrate headgear with flexible yoke and incorporated seal ring.

In FIG. **12-8**, the headgear includes Breathoprene headgear straps **2753** and yoke **2755** molded of a thin thermoplastic/silicone material. As illustrated, the yoke **2755** has a varying profile along its length. Also, a yoke ring **2756** is integrated to the proximal end of the yoke **2755** and branding **2780** is incorporated into a distal end section thereof. In an embodiment, no headgear straps may be provided along the yoke and a slot may be provided at the distal end of the yoke for engaging straps that cup the patient's head.

In FIG. **12-9-1**, the headgear includes Breathoprene headgear straps **2853** and yoke **2855** constructed of a thin thermoplastic/silicone material. As illustrated, the yoke **2855** has a general L-shape with a seal ring **2856** provided to the proximal end and branding **2880** incorporated into a distal end section. As shown in FIG. **12-9-2**, the thermoplastic/silicone yoke **2855** may include corrugations, arcuate cut outs, thinned out localized section, or ridges **2888** to encourage bending or flexing so that the yoke **2855** can contour to the profile of the user's face (e.g., similar to swimming goggle straps). The thermoplastic/silicone yoke **2855** may maintain strength in the direction of the seal (e.g., into the patient' nose) which is essentially parallel to the direction of the force vector created by the straps.

In FIG. **12-10**, the headgear includes Breathoprene headgear straps **2953** and yoke **2955** constructed of a thin thermoplastic/silicone material. As illustrated, the proximal end of the yoke **2955** includes a seal ring **2956** and the distal end of the yoke **2955** includes a Y-shaped configuration **2981**. The Y-shaped distal end of the yoke **2955** provides a rigidizer along two different straps and hence in two different vectors. Also, the strap portion adjacent the distal end of the yoke **2955** may include surface texture **2980** for a branding feature.

In FIG. **12-11-1**, the headgear includes headgear straps **3053** that cup the patient's occiput and yoke **3055** to couple the headgear straps **3053** with the nasal prong assembly. The yoke **3055** includes a narrow construction and may be formed of a silicone material. As illustrated, the proximal end of the yoke **3055** includes a seal ring **3056** and the distal end of the yoke **3055** includes a cross-bar **3066** for adjustable attachment with the headgear straps **3053**. Also, a foam pad **3090** is provided to the yoke **3055** and adapted to contact the side of the patient's face. As shown in FIG. **12-11-2**, the foam pad **3090** is molded with an undercut so that it can wrap over the yoke **3055**. That is, the undercut of the foam pad **3090** naturally captures the yoke **3055** and holds the foam pad **3090** in place.

Foam Section Attached to Yoke

In FIG. **12-15-1**, the headgear includes headgear straps **3453**, molded plastic yokes **3455** that extend along respective sides of the patient's face, and a foam section or insert **3490** (e.g, constructed of viscoelastic foam) attached to the yoke **3455** and adapted to contact the side of the patient's face. As shown in FIG. **12-15-2**, the foam section **3490** may be molded with an undercut shape so that it can wrap over or capture the yoke **3455**. That is, the molded undercut of the foam section **3490** naturally captures the yoke **3455** and holds the foam section in place. In an embodiment, the undercut shape may be provided to only one side of the foam section **3490** such as that shown in FIG. **12-15-1**.

The viscoelastic foam section **3490** provides a "high comfort" material around the sensitive cheek bone (zygomatic) region of the patient's face, which appears to be one of the primary sources of discomfort for headgear.

Also, this embodiment provides increased levels of usability (e.g., particularly during fitting and adjustment) for intuitive features such as single piece 3D shaped headgear and lateral headgear tension adjustments.

Silicone/Thermoplastic Foam Attached to Yoke

In FIG. **12-16-1**, the headgear includes headgear straps **3553**, molded plastic yokes **3555** that extend along respective sides of the patient's face, and a foam section or insert **3590** (e.g, injection molded of silicone/thermoplastic foam) attached to the yoke **3555** and adapted to contact the side of the patient's face. As shown in FIGS. **12-16-2** and **12-16-3**, the silicone/thermoplastic foam section **3590** may be molded with an undercut shape so that it can wrap over or capture the yoke **3555**. That is, the molded undercut of the foam section **3590** naturally captures or slips over the yoke **3555** and retains the foam section **3590** in position. In addition, this arrangement provides foam to both the inside and outside radii of the yoke **3555**. In an embodiment, the foam may be visco elestic foam and/or may provide heat activated memory.

The silicone/thermoplastic foam section **3590** provides a "high comfort" material around the sensitive cheek bone (zygomatic) region of the patient's face, which appears to be one of the primary sources of discomfort for headgear.

Also, this embodiment provides increased levels of usability (e.g., particularly during fitting and adjustment) for intuitive features such as single piece 3D shaped headgear and lateral headgear tension adjustments.

2.5.3 Alternative Headgear Yoke

As shown in FIGS. **19-1** to **19-4**, each yoke **5055** includes a first end portion **5055(1)** adapted to engage a respective side of the frame **5030** and provide stability and support to the frame and nasal prong assembly during use, a second end portion **5055(2)** adapted to engage a respective end of the rear strap **5057**, and an intermediate portion **5055(3)** between the first and second end portions **5055(1)**, **5055(2)** adapted to add rigidity to a respective side strap **5053**.

The yokes **5055** include one or more of the following functions: attach headgear to the frame, provide stability and support to the frame and nasal prong assembly during use, provide a yoke to frame interface, retain the frame during use, easy assembly/disassembly from the frame, rotate relative to the frame and allow adjustment to suit nasolabial angle, durability (e.g., 12 months or more), wide fit range (e.g., 95% of male and female population), visually minimal and unobtrusive, comfortable, provide a region, or regions, for the application of branding, and/or ease-of-use.

The yokes **5055** are structured and designed to improve visual integration and simple clean lines and forms. For example, the contoured form of each yoke breaks up flat faces to create highlight/shadow line and give an overall smaller impression. The single stitch and recessed groove used to attach the yoke to the respective strap provides a clean, streamlined form when assembled. The second end portion of the yoke is structured to leave minimum edges to lift away from the headgear strap if glued. The overall size of the yoke may be dictated by the various functions of the yoke to frame interface, e.g., minimum overall size and width while providing torque and rotation, retention of frame, and sufficient strength in area between yoke to frame and yoke to headgear strap.

2.5.4 Cheek Support

In accordance with an embodiment of the invention, cheek supports **62** are provided (e.g., see FIGS. **6-1** to **6-4**). These function to enhance stability of the mask system on the face. In one aspect they enable headgear forces to be directed more onto the front of the face, e.g. the maxilla and or zygoma.

The first end portion **55(1)** also includes a curved protrusion in the form of a cheek support **62** that curves forward or inwardly of the yoke ring **56**. The cheek support **62** is attached to an end portion **63** of the side strap **53** (e.g., via stitching, glue, etc.) as shown in FIGS. **1-1** and **6-4**. The cheek support **62** follows the cheek contour and is adapted to engage or hug the patient's cheek to provide stable cheek support. That is, the cheek support **62** stably supports the nasal prong assembly **20** in position and retains overall sealing stability.

The cheek support **62** provides a feature which both cushions against the cheeks and hugs the face evenly without introducing pressure points. This arrangement may reduce the strap tension required to maintain a seal and optimize patient comfort. Thus, the positioning of the cheek supports **62** on the headgear yokes **55** should discourage the user from applying excess headgear tension or over-tightening of the headgear, which can force the nasal prongs to compress into the naris region and affect sealing effectiveness.

The cheek supports **62** effectively takes the prongs' responsibility to provide stability to the mask system. The prongs can hence work almost independently to the supplied headgear tension, focusing on its own expansion to provide a secure seal.

FIG. **6-4** illustrates a version of the cheek support **62** with the strap portion **63** attached thereto. As illustrated, the strap **63** bends around the cheek support **62** to suit the contours of the patient's face. The cheek support **62** may be flexible or provide a lever action which flexes to suit the patient.

FIGS. **7-1** and **7-2** schematically illustrate how the supplied headgear tension has a different effect on the headgear **50** according to an embodiment of the present invention and ResMed's Mirage Swift headgear **150**. On the Swift headgear **150**, only a small section of the padded headgear is used to absorb the headgear tension in order to stabilize the mask. As a result, a large percentage of the headgear tension is applied directly through the prongs (see FIG. **7-1**), pressing directly onto the septum and nostrils, which are very sensitive areas. For some patients, their minimum amount of securing headgear tension is sufficient to completely compress the pillows into the nose. In contrast, the cheek supports **62** on the headgear **50** transfers the bearing surface area from the prongs such that the headgear tension can be dispersed across the less sensitive cheek area and produce acceptable mask comfort. Beneficially, since mask stability is attributed to the entire headgear, sealing force is left attributed to the prongs. Thus, the cheek supports **62** take in most of the headgear tension, preventing the prongs from being compressed.

As shown in FIGS. **6-1** to **6-4**, rib-strengthened brackets **64** support the yoke ring **56** on the yoke **55**. Such brackets **64** add rigidity to the yoke ring **56** without affecting the flexibility of the yoke **55**. That is, the brackets **64** help retain the yoke ring **56** and hence the frame of the nasal prong assembly **20** in position and prevent the frame from compressing the nasal prongs against the naris region when the headgear **50** is adjusted/tightened.

In addition, the cheek support **62** and/or brackets **64** may help to reduce tube drag which can cause undesired shifting of the frame and/or affect sealing stability.

As shown in FIGS. **13-1** to **13-4**, **14-1**, and **19-1** to **19-5**, each cheek support **5084** curves forward of the yoke to frame interface **5085**. The cheek support **5084** is attached to an end portion **5063** of the side strap **5053** (e.g., via stitching, glue, etc.). In an embodiment, the end portion **5063** of the side strap **5053** may overhang the cheek support **5084** by about 2.5 mm at the tip and about 4.0 mm at the upper and lower sides. However, the strap overhang may have other suitable dimensions, e.g., depending on application, patient comfort, etc.

The cheek support **5084** follows the cheek contour and is adapted to engage or hug the patient's cheek to provide a stable cheek support and hence provide additional support to the patient interface. That is, the cheek support **5084** stably supports the nasal prong assembly **4020** in position and retains overall sealing stability.

The cheek support **5084** is adapted to rest on the cheeks of the patient in use, e.g., below the cheek bone. Benefits of this location include one or more of the following: soft skin which is pliable, not sensitive, cheek bone support structure, and/or unobtrusive location.

The curvature of the cheek support **5084** may be determined from anthropometric analysis to provide a good fit for a wide range of patient head sizes. In the illustrated embodiment, the cheek support **5084** is raised vertically on the cheek (e.g., by about 2 mm with respect to the cheek support **62** described above) to provide preferred stability and comfort for this embodiment of the patient interface.

In an embodiment, the cheek support **5084** may be flexible in order to conform to the contours of the patient's face. Such flexibility may be provided by the selected material and/or thickness of the cheek support (e.g., 1.2 mm nylon material), and/or the cantilever arrangement of the cheek support (e.g., 22 mm cantilever arm) which may be locally narrowed to aid flexibility.

In an embodiment, as shown in FIG. **19-18**, the distance D**1** between cheek supports **5034** may be about 55 mm, which provides a distance D**2** of about 50 mm with the headgear strap **5053** (e.g., 2.5 mm strap backing on each side). Such distance provides sufficient clearance to accommodate the width of the patient's nose for a wide range of patients, e.g., 97.5% male width is 39 mm (provides over 11 mm clearance). However, such distance may be increased, e.g., 60-65 mm distance between cheek supports.

The cheek supports **5084** provide a three-dimensional gripping mechanism, for sufficient comfort and mask stability, may allow less headgear tension to seal the nasal prongs, and/or may help to reduce tube drag which can cause undesired shifting of the frame and/or affect sealing stability. Moreover, the cheek supports **5084** isolate seal forces from stability forces, so that headgear tension is applied to the cheek supports rather than to the upper lip and/or to the prongs (preventing the prongs from being compressed).

In alternative embodiments, more than one cheek support may be provided, and/or the one or more cheek supports may be provided at different angles.

The support arm **5080** supports the yoke to frame interface **5085** on the yoke **5055**. Moreover, the support arm **5080** provides support and stability of the frame **5030** and nasal prong assembly **5020** attached thereto.

As shown in FIG. **19-16**, the lever length D**1** of the yoke **5055** between attachment of headgear strap and frame has been increased (e.g., with respect to the yoke **55** described above). The increase in length provides sufficient clearance to accommodate the gusseted nasal prong assembly **5020**.

As shown in FIGS. **19-1** to **19-5**, the support arm **5080** is contoured or c-shaped to strengthen the support arm **5080** along its length. Specifically, the support arm **5080** has a generally C-shaped cross-sectional configuration along its length, which provides structural rigidity to the support arm **5080** and hence overall stability to the yoke **5055**. As shown in FIGS. **19-17-1** to **19-17-4** which illustrate cross-sections along the length of the support arm **5080**, the support arm **5080** transitions from a relatively flat section (FIG. **19-17-4**) to the three-dimensional C-shaped section (FIG. **19-17-2**). The flat section (FIG. **19-17-4**) provides a flat contact surface for engaging the respective headgear strap. The depth of the upper and lower ribs (i.e., the depth of the upper and lower walls of the c-shaped section) may be determined by the width of the gusset **5022** of the nasal prong assembly **5020**.

Along with the differing structural shape along its length, the wall section in the support arm **5080** is thicker than the wall section in the remaining portions of the yoke **5055** (e.g., wall section of support arm **5080** increases from about 1.2 mm (primary part wall thickness) to about 1.5 mm) to provide further rigidity.

The rounded, outwardly facing surface **5080.1** of the support arm **5080** (see FIG. **19-2**) provides a branding surface for branding, e.g., lettering and/or logo. Such branding may be molded and/or printed onto the support arm. However, it should be appreciated that branding may be provided to other suitable portions of the yoke.

2.5.5 Increase Friction and Stability

The headgear **50** and/or nasal prong assembly **20** may include structure to improve stability. For example, such structure may increase friction with the patient's face, and the added friction enhances stability of the mask system on the patient's face in use.

Wider Headgear Straps

In an embodiment, the width of the headgear straps may be increased (e.g., with respect to ResMed's Swift mask) in order to increase the friction provided by the headgear straps. That is, the straps may be wider to increase the contact area with the patient's face, which provides more friction. The added friction increases stability which improves comfort. In addition, the wider straps may help to reduce irritation to the patient's cheeks.

FIG. **10-1** illustrates a headgear strap section including a headgear strap **753** and headgear yoke **755** provided the headgear strap **753** (e.g., via stitching). In such embodiment, the width w of the strap on each side of the yoke is about 5-9 mm. In contrast, known embodiments include a strap width on each side of the yoke of about 4.5-5 mm.

FIGS. **10-2-1** and **10-2-2** illustrate another embodiment including wider headgear straps. In this embodiment, the headgear straps **853** may be constructed of a foam material to further increase friction. In addition, the headgear strap **853** may include an extended portion **863** that extends between the nasal prong assembly **820** and the patient's cheek to improve stability.

In an alternative embodiment, the width of the yoke may be thinner in order to increase the width of the strap on each side of the yoke.

Reduction of Headgear Marking/Irritation

An increase in strap width on a side of the yoke may also help to reduce headgear "cheek mark".

In the illustrated embodiment, the headgear closely follows the profile of the patient's face and "hugs" the cheek region. The Breathoprene straps provide sufficient contact area and friction to stabilize the interface and the yokes function as a rigid element that retain the shape of the headgear.

A common side effect with known headgear is "cheek mark", which is a temporary marking left along the side of the patient's face and cheek region upon removing the interface, after an extended period of wearing. This region R is displayed in FIG. **10-3-1** with respect to ResMed's SWIFT headgear **150**. As illustrated, the temporary marking appears to follow the profile of the headgear straps along the side of the face (e.g., swoosh mark). Also, yokes attached to the strap by stitching may leave a stitch mark and/or indentations along the perimeter of the yoke with stitching indentations on the inside face of the strap material.

According to an embodiment of the present invention, the amount of headgear strap material on a side of the yoke facing inwardly (i.e., towards the patient's nose) may be increased to reduce facial marks left by the headgear.

FIG. **10-3-2** illustrates a known embodiment in which the width w of the strap **153** on each side of the yoke **155** is about 5 mm. In such arrangement, the strap material **153** may cut into the patient's cheek and create a cheek mark.

FIG. **10-4** illustrates a headgear section according to an embodiment of the present invention in which the strap **953** on the side of the yoke **955** facing the patient's nose has a width w of about 8 mm. Such arrangement increases the cantilever nature of the strap **953** so that the strap **953** becomes more flexible and does not substantially cut into the patient's cheek to create a mask.

FIGS. **10-5** and **10-6** illustrate alternative embodiments of headgear structured to reduce facial marks. In FIG. **10-5**, the strap **1053** includes a total width w**1** of about 20 mm and includes a width or overhang w**2** of about 5.5 mm on each side of the yoke **1055**. In FIG. **10-6**, the strap **1153** includes a total width w**1** of about 25 mm wide and includes a width or overhang w**2** of about 8.5 mm on each side of the yoke **1155**.

Alternative embodiments to eliminate or reduce facial marks occurring on the cheeks include: reducing the density of the headgear strap material; introducing a softer strap surface material; introducing a highly compliant element to the inside surface of the strap, removing the sharp 90° edge that sits up against the face (e.g., change profile of edge);

improving lateral flexibility of the strap and yoke; altering the way in which the yokes interface with the frame; imbedding a component or material that provides the function of the yokes within a soft padded outer layer (e.g., a "sock" like padded outer layer); introducing a material that provides flexibility along a single plane/direction (e.g., it will flex and contour to the shape of the face while providing a rigidizer function along an adjustment plane); eliminating the stitching used to hold the yokes; adding a layer of 3 mm or 4 mm flocking to the inside of the strap; raising the headgear straps off of the face along the cheek region so that it is only making contact on the upper lip and side of head; introducing a molded foam component that is transfer molded to a plastic headgear component; reducing the overall material thickness of the headgear straps; using a thin textile, e.g., linen, rather than a plastic and foam component (e.g., this arrangement may reduce the overall height of the straps); and/or constructing the headgear from a thin textile that is stiffened in an isolated region to provide the rigidizing function currently fulfilled by the yokes (e.g., stiffening may be provided by impregnating the material with an epoxy (e.g., screen-printing)).

Also, alternative embodiments to eliminate or reduce marking/irritation occurring on the upper ear lobes include: introducing a lower density strap material; altering the geometry of the headgear to avoid the ears completely; using a softened rounded edge material or soft padded component where the headgear contacts the ears; providing headgear that sits over the sides of the ears (e.g., headphone style); incorporating a rotational adjustment for the back strap so that the strap can be positioned to clear the ears; using the ears as a point of location/stability (e.g., eye glasses) which may aid in correctly locating the interface or improving overall stability; and/or eliminating the back strap to avoid the ears.

Friction Pads Provided to Headgear

In another embodiment, a friction pad may be provided to the headgear to increase friction. For example, FIG. **10-7-1** illustrates a lower headgear strap section including a headgear strap **1253** and headgear yoke **1255** (including yoke ring **1256**) provided the headgear strap **1253**. As illustrated, a friction pad **1270** (e.g., constructed of silicone) may be provided to the yoke **1255** and adapted to contact the patient's cheek or cheekbone region to improve stability and provide additional support to the seal region.

In an embodiment, such friction pad **1270** may be retrofit to ResMed's Swift headgear. For example, FIGS. **10-7-2** and **10-7-3** illustrate friction pads **1270** provided to yokes **155** of ResMed's Swift headgear. In the illustrated embodiment, each friction pad **1270** may include a retainer **1271** sized and configured to be accepted in an opening provided in the yoke **155**. As illustrated, the friction pads **1270** contour to the patient's face to improve stability.

Friction Pads Provided to Nasal Prong Assembly

In another embodiment, a friction pad may be provided to the nasal prong assembly to increase friction. For example, FIGS. **10-8-1** to **10-8-3** illustrate wings **1372** (e.g., constructed of silicone) provided to the base or body **1322** of the nasal prong assembly **1320** and adapted to contact the patient's cheeks or cheekbone region to improve stability and provide additional support to the seal region. As shown in FIG. **10-8-3**, the wings **1372** contour to the patient's face in use.

In embodiments, the wings may extend from the base of the nasal prong assembly or the wings may extend from the frame.

Foam Padding Provided to Headgear

In another embodiment, foam padding may be provided to the headgear to increase friction. For example, FIG. **10-9-1** illustrates a lower headgear strap section including a headgear strap **1453** (e.g., constructed of Breathoprene) and headgear yoke **1455** (including yoke ring **1456**) provided the headgear strap **1453**. As illustrated, foam padding **1474** may be provided to the rear of the strap **1453** and between the strap **1453** and the yoke **1455**.

As shown in FIGS. **10-9-2** and **10-9-3**, the foam padding **1474** is suitably contoured so that the foam padding **1474** guides the strap **1453** along the curvature of the patient's face to increase surface area and facial contact provided by the strap **1453**, and hence improve stability.

In an alternative embodiment, as shown in FIG. **10-9-4**, foam padding may not be provided between the yoke and the strap. As illustrated, the strap **1453** may form a wing adapted to engage the patient's face in use.

Alternative Embodiments to Improve Stability

In alternative embodiments, additional support and stability to the seal region may be provided by wings or straps that sit under the mouth or below the chin in use (e.g., chin pad, chin strap).

For example, an exemplary chin strap may follow the plane of the headgear straps/yokes to run down and under the chin, and such chin strap may also support a secondary function of holding the mouth closed.

In another embodiment, a loop may contact the patient's face around the nose to provide addition support to the seal region.

Other embodiments to improve headgear stability includes: provide additional support through adhering the silicone nasal prongs to the skin; provide additional support through increasing contact between the prong and the patient's top lip; provide additional support through introducing an inflatable hood to the prongs that expands up against the walls of the nasal passage to hold the interface in place; provide additional support through a silicone skeleton that lies across the upper lip and cheek bone region which may eliminate all rigid plastic elements from the face (e.g., headgear may no longer have to function to hold the seal in as this is facilitated by the skeleton, rather the headgear functions only to hold the skeleton against the face); provide gel padding that sits against the face; and/or provide a mouthpiece that holds the frame in place.

Crown Portion

Crown Strap Style Headgear

FIGS. **12-19** to **12-21-3** illustrate headgear having a crown strap style.

In FIG. **12-19**, the headgear includes an arrangement similar to that shown in WO 2006/130903, which is incorporated herein by reference in its entirety. As illustrated, the headgear includes headgear straps **3853** that cup the crown of the patient's head, and yokes **3855** provided between the headgear straps **3853** and the nasal prong assembly. The headgear straps **3853** include side strap portions **3853(1)**, bridge strap portions **3853(2)**, and crown strap portions **3853(3)**. The side strap portions **3853(1)** may provide lateral Velcro adjustment with respect to the yokes **3855**. Also, an additional adjustment buckle may be provided along the straps at the top of the patient's head. Each yoke **3855** includes a yoke ring **3856** to engage the nasal prong assembly and a cross bar **3866** to engage a respective side strap **3853(1)**.

In FIGS. **12-20-1** and **12-20-2**, the headgear is similar to that shown in FIG. **12-19**. In contrast, the headgear includes an extra bridge strap. Specifically, the headgear straps **3953** include side strap portions **3953**(**1**), upper bridge strap portions **3953**(2U), lower bridge strap portions **3953**(2L), center strap portions **3953**(**4**) between the upper and lower bridge strap portions, and crown strap portions **3953**(**3**). The side strap portions **3953**(**1**) may provide lateral Velcro adjustment with respect to the yokes **3955**. In use, the extra bridge strap may help to balance headgear forces.

In FIGS. **12-21-1** to **12-21-3**, the headgear is similar to that shown in FIGS. **12-20-1** and **12-20-2**. In contrast, no center strap portion is provided between the upper and lower bridge strap portions. Thus, the headgear straps **4053** include side strap portions **4053**(**1**), upper bridge strap portions **4053**(2U), lower bridge strap portions **4053**(2L), and crown strap portions **4053**(**3**). The side strap portions **4053**(**1**) may provide lateral Velcro adjustment with respect to the yokes **4055**.

Rear Strap Portion

FIG. **9** illustrates another embodiment of a rear strap **657**. As illustrated, the central portion of the rear strap **657** includes an increased width w with respect to the end portions. In addition, a hook material **668** is inset from respective ends of the strap **657** (e.g., attached by welding, stitching, etc.) so that the respective ends of the strap **657** provide a pull tab **669** to facilitate adjustment. The hook material **668** is adapted to engage remaining portions of the strap (e.g., loop type material) to secure the strap **657** in position.

Alternative Headgear Materials

FIGS. **12-5** to **12-7-2** illustrate alternative arrangements of headgear material.

In FIG. **12-5**, headgear straps **2453** of the headgear are constructed of Breathoprene material with company branded microfibre **2484** on an inside surface (i.e., surface adapted to engage the patient's head in use). Similar to FIG. **12-3**, the yoke **2455** may include a distal end section with a cut-out logo **2480**.

In FIG. **12-6**, headgear straps **2553** of the headgear are constructed of Breathoprene material, and at least a section of the material is perforated **2586**. For example, selected portions of the headgear straps **2553** may include perforated Breathoprene material, or all the headgear straps **2553** may include perforated Breathoprene material. Also, a thermoformed rigidizer section **2555** may be provided to the headgear straps **2553**, e.g., to secure the nasal prong assembly in position.

In FIG. **12-7-1**, the headgear straps **2653** of the headgear are constructed of Breathoprene material, and a heat transfer label **2655** (e.g., constructed of foam) is provided to each side strap (e.g., label ironed onto strap) to provide a rigidizing function. As shown in FIG. **12-7-2**, the heat transfer label **2655** may include corrugations or cut outs **2688** to encourage bending or flexing so that the heat transfer label **2655** can contour to the profile of the user's face. Also, the heat transfer label **2655** may provide an opportunity for a wide range of branding designs (e.g., branding printed to label). The seal ring that engages the frame of the nasal prong assembly may be constructed of strap material or silicone, for example, and provided to the end of the label. In an embodiment, selected portions of the label may be treated.

Removable Foam Sock

In FIG. **12-14-1**, the headgear includes headgear straps **3353**, molded plastic yokes **3355** that extend along respective sides of the patient's face, and a removable sock **3392** (e.g., constructed of foam) that encloses at least a portion of the yoke **3355**. As shown in FIGS. **12-14-2** and **12-14-3**, the foam sock **3392** may be constructed of open or closed cell foam and forms a sleeve that sheathes or encloses the yoke **3355**. In the illustrated embodiment, the foam sock **3392** is generally L-shaped, and includes a cut-out **3393** to positively locate and properly position the foam sock **3392** with respect to the yoke **3355**. The foam sock **3392** may be a closed cell extruded section or a thin slab of open cell foam rolled back on itself and glued to form the required section. Also, the foam sock **3392** may be available in a variety of colors and sizes, e.g., foam sock may extend along portions of the headgear straps and/or nasal prong assembly. In addition, the foam sock **3392** may provide various aesthetic and branding possibilities.

The foam sock **3392** provides a "high comfort" material around the sensitive cheek bone (zygomatic) region of the patient's face, which appears to be one of the primary sources of discomfort for headgear.

Tube Retainer

A tube retainer or retaining strap (not shown) may be provided to an upper strap portion **53**(**1**) to retain the air delivery tube when in an upward position along the side of the patient's head (e.g., tube retainer wraps around both the tube and strap portion or buckle). An exemplary tube retainer is described in U.S. Pat. No. 7,318,437 and U.S. Patent Application Publication No. 2006-0137690, each of which is incorporated herein by reference in its entirety.

FIGS. **5-47-1** to **5-47-6** illustrate a soft-loop tube retainer **6361** according to an embodiment of the present invention. As illustrated, the tube retainer **6361** includes a first strap portion **6361**(**1**) adapted to wrap or loop around one of the headgear straps and a second strap portion **6361**(**2**) provided to the first strap portion **6361**(**1**) and adapted to wrap or loop around the air delivery tube. The tube retainer **6361** may be provided to the headgear at any suitable position along the upper strap portions to retain the air delivery tube along the side or over the top of the patient's head. Also, the tube retainer **6361** may be structured to wrap or loop around two or more different size tubings, e.g., short tube and 2 m air delivery tube.

In the illustrated embodiment, the tube retainer **6361** is integrally formed in one-piece (e.g., cut from headgear material (e.g., Breath-O-Prene™) or other suitable soft and flexible material) with the second strap portion **6361**(**2**) extending transverse to the first strap portion **6361**(**1**). As illustrated, the second strap portion **6361**(**2**) is thinner than the first strap portion **6361**(**1**), and each strap portion includes a Velcro® tab **6362** adapted to secure the respective loop in position. The first strap portion **6361**(**1**) tapers towards respective ends, and includes a tab **6363** to facilitate connection with the second strap portion **6361**(**2**). FIG. **5-47-6** illustrates the orientation of looping of the first and second strap portions **6361**(**1**), **6361**(**2**).

In an alternative embodiment, a tube retainer or retaining strap may be provided to headgear to retain the air delivery tube in a position over the top of the patient's head (i.e., tube runs over the head as opposed to along the side of the head). This arrangement allows the patient to assume different sleep positions, e.g., sleeping on side head, back of head, etc.

For example, a tube retainer or retaining clip may be provided to a headgear buckle (e.g., in the position of headgear buckle **60** shown in FIG. **1-1** or headgear buckle **5060** shown in FIG. **13-4**) to retain the air delivery tube when in an upward position along the top or side of the patient's head (e.g., tube retainer clips around the tube and locks into the strap portion). This arrangement allows the patient to assume different sleep positions, e.g., sleeping on side head, back of head, etc.

In the illustrated embodiment, the tube retainer **5561** (FIGS. **5-42-1** to **5-42-6**) is structured to adjustably interlock with a headgear buckle **5560** (FIGS. **5-43-1** to **5-43-7**). The tube retainer **5561** (e.g., constructed of plastic) is structured to retain at least two different sized tubings, interface with the headgear buckle **5560**, rotate within the headgear buckle for desired positions for side sleeping, connect/disconnect from the headgear buckle, and does not allow tube slide until a certain tube drag limit to avoid tube damage. As illustrated, the tube retainer **5561** is generally round (e.g., circular or oval) with an opening **5561.1** at its proximal end. The air delivery tube may be passed through this opening **5561.1** via extension of the tube retainer **5561**. Slides or guiding surfaces **5561.2** may be placed on either side of the opening **5561.1** to aid in the positioning and/or insertion of the air delivery tube. Also, each of the inner radial arms or walls **5561.3** of the tube retainer **5561** include multiple teeth **5561.4** (e.g., 3, 4 or 5 teeth, or more or less) to better support the air delivery tube once clipped into the tube retainer **5561**. In addition, one or more teeth **5561.5** may be provided to support the air delivery tube. The arms or walls **5561.3** of the tube retainer **5561** are structured to flex to accommodate two or more different size tubings, e.g., short tube and 2 m air delivery tube (two different diameters), and do so over the lifetime of the product.

The tube retainer **5561** has two buttons **5561.6** at its distal end that may be resiliently pressed together to align the tongues **5561.7** together. Once aligned, the buttons **5561.6** may be engaged with the opening **5560.1** on the headgear buckle **5560** by releasing the buttons **5561.6** and allowing them to flex into the opening **5560.1**. This mechanically locks the tube retainer **5561** with the headgear buckle **5560**, and allows the tube retainer **5561** to rotate relative to the headgear buckle **5560**. However, alternative methods of fixation may be used, e.g., buttons engaged with respective grooves on the buckle, adhesives.

As illustrated, the headgear buckle **5560** includes opposing locking portions **5560.2** adapted to be removably and adjustably coupled with respective headgear straps, e.g., headgear strap may be wrapped around the cross-bar of the associated locking portion in a known manner.

Also, the tube retainer **5561** may be rotated relative to the headgear buckle **5560** to adjust its position. A detent assembly assists in restraining the tube retainer **5561** at the desired position, and provides tactile feedback with the motion of the tube retainer **5561**. Specifically, the opening **5560.1** of the buckle **5560** includes detents **5560.3** that interact with projections **5561.8** provided on each of the buttons **5561.6** of the tube retainer **5561**. In addition, the buckle **5560** includes a series of recesses **5560.4** that interact with projections **5561.9** provided on the underside of the tube retainer **5561**. As the tube retainer **5561** is rotated or adjusted, the projections **5561.8**, **5561.9** of the tube retainer **5561** will move into and out of engagement with respective detents **5560.3**/recesses **5560.4** of the buckle **5560**. The projections **5561.8**, **5561.9** will be seated within respective detents **5560.3**/recesses **5560.4** to assist in restraining the tube retainer **5561** at the desired position.

Alternative Tube Retainers and Buckles

FIGS. **5-48** to **5-86** illustrate tube retainers **7100** and headgear buckles **7000** structured to manage tubing according to alternative embodiments of the present invention.

In each embodiment, the tube retainer is structured to stabilize the air delivery tube increasing the opportunity for an effective seal to form. The stabilization of the air delivery tube will also enhance patient comfort by allowing for a larger range of sleeping positions and reducing the incidence of irritation caused by tubing interference.

The tube retainer is a structure designed to maintain the air delivery tube in a fixed position. The tube retainer may be formed from any semi-rigid or rigid material such as Hytrel, HTPC.

The buckle is a joining member between two headgear straps that allows the tension in the headgear to be adjusted (e.g., in the position of headgear buckle **60** shown in FIG. **1-1** or headgear buckle **5060** shown in FIG. **13-4**). The buckle may be formed from any semi-rigid or rigid material such as Hytrel, HTPC.

In the embodiments described below, each tube retainer **7100** (FIGS. **5-68** to **5-86**) may be connected to each buckle **7000** (FIGS. **5-48** to **5-67**). In an embodiment, each tube retainer **7100** may be easily and repeatedly connected to each buckle **7000**. In an embodiment, each tube retainer **7100** may be rotated, either fixed or freely, once connected to the buckle **7000**.

Buckle

As shown in FIGS. **5-48** to **5-67**, each buckle **7000** includes two openings or strap locks **7040** (e.g., laddered strap lock) for engagement with upper strap portions of the headgear (e.g., headgear strap may be wrapped around the cross-bar of the associated strap lock in a known manner) and a cutout section or keyhole **7060** in the center for engagement with a tube retainer.

In an embodiment, each buckle **7000** may have a height H, e.g., 2 mm, as shown in FIG. **5-48**. This embodiment may be considered a low profile buckle, which can be beneficial as it less obtrusive and more comfortable for the patient. In FIG. **5-48**, the buckle includes a cutout **7090** along its outer edges on each side of the keyhole **7060**. In an embodiment, such cutout **7090** may be more curved along its length as shown in FIG. **5-49**, which soft curved edges increase comfort and add to the visual appeal of the headgear.

Strap Locks

In an embodiment, the strap locks **7040** on the buckle **7000** may have a cutout in the middle or anywhere along its longest side to form gap **7041** and teeth **7042** as demonstrated in FIGS. **5-48** to **5-53**. The gap **7041** allows for easy engagement and disengagement of the upper strap portions of the headgear. In an alternative embodiment, the teeth **7042** may have tapered tips **7043** to enable the headgear straps to slide more readily through gap **7041**, as shown in FIG. **5-50**. In yet another embodiment, the teeth **7042** may have tapered edges **7044** to enable the headgear straps to slide more readily through gap **7041**, as shown in FIG. **5-51**. The strap locks **7040** may also have a ladder-lock profile **7045** as shown in FIG. **5-53**.

Keyhole

The keyhole **7060** may be located in the center of the buckle **7000**, however it may also be located at other suitable locations on the buckle, e.g., offset from the center of the buckle.

The keyhole **7060** may have a general key shape as shown in FIG. **5-52**. Alternatively, the keyhole **7060** may assume other suitable shapes, e.g., generally circular shaped as shown in FIGS. **5-56** to **5-67**. In embodiments, the keyhole **7060** may have shaped (e.g., square, circular, triangular) apertures **7061** (e.g., 1, 2, 3, or more shaped apertures) extending from the keyhole **7060**. In an embodiment, the apertures **7061** may have a generally conical shape as shown in FIG. **5-66**. These apertures **7061** can be evenly spaced (e.g., provided every 90°) or unevenly spaced. These apertures are to allow rotation and thus adjustment of the tube retainer when connected to the buckle. The keyhole **7060** may have a tapered entry **7062** as shown in FIG. **5-67**.

Tapered entry **7062** provides a lead-in for the tube retainer **7100** to ensure correct alignment of tube retainer **7100** with buckle **7000**.

The keyhole **7060** may also have one or more additional holes **7065** about the keyhole **7060** as shown in FIGS. **5-54** to **5-63**. In an embodiment, the additional holes **7065** may follow the general path of the keyhole **7060** (as shown in FIGS. **5-54** and **5-55**) or the additional holes **7065** may follow a path unlike the keyhole **7060** (as shown in FIG. **5-56**). In embodiments, the additional holes **7065** may be substantially the same length as keyhole **7060**, longer than the keyhole **7060** (as shown in FIGS. **5-56** and **5-63**), or shorter than the keyhole **7060** (as shown in FIGS. **5-54** and **5-55**). The width of the additional holes **7065** may be relatively thin (e.g., 0.5 mm, see FIGS. **5-57** and **5-59**) or relatively thick (e.g., 4 mm, see FIGS. **5-58** and **5-61**) and the thickness may vary along its length. In another embodiment, the additional holes **7065** may vary in number, e.g., there may be 1, 2, 3, 4, or more additional holes (see FIG. **5-59**). In yet another embodiment, the additional holes **7065** may adjoin keyhole **7060** (as shown in FIGS. **5-56** to **5-59**) or may be separated from keyhole **7060** (as shown in FIGS. **5-54** and **5-55**).

The additional holes **7065** are provided to allow spring or resilient flexibility during engagement of the tube retainer **7100** with the keyhole **7060** and also during rotation of the tube retainer **7100** when engaged with the keyhole **7060**. Adjusting the length of holes **7065** will alter the spring properties and thus ease of engagement and disengagement and also rotation of the tube retainer **7100** with the buckle **7000**.

In an embodiment, a locking collar **7070** may be provided around keyhole **7060** (see FIG. **5-60**) or around the keyhole **7060** and additional holes **7065** (see FIGS. **5-62** and **5-63**). The locking collar **7070** may follow the path of the keyhole **7060**, as shown in FIGS. **5-60** and **5-65**. The locking collar **7070** may extend around the entire perimeter of the keyhole **7060** (see FIGS. **5-60** and **5-65**) or may follow a portion or portions of the keyhole **7060** (see FIG. **5-64**). Locking bumps **7071** may be provided along the locking collar **7070** (shown in FIG. **5-60**) to allow for fixed rotation of the tube retainer **7100** with respect to the buckle **7000** (e.g., detent assembly). The locking bumps **7071** may be generally hemispherical (as shown in FIG. **5-60**), conical, or any other suitable shape. The number of locking bumps **7071** may be varied (e.g., 3, 6, or other suitable number) to alter the number of fixed positions of the tube retainer **7100** with respect to the buckle **7000**.

Tube Retainer

As shown in FIGS. **5-68** to **5-82**, each tube retainer **7100** has a generally rounded curvature, an opening to allow a tube to pass through its circumference, and a tab adapted to engage with a buckle **7000**.

Arms

In the illustrated embodiments, each tube retainer **7100** has two arms **7130** each with a generally rounded curvature. In an embodiment, the arms **7130** may be generally circular as shown in FIG. **5-68** or may be generally elliptical as shown in FIG. **5-69**. In an alternative embodiment, the arms **7130** may be irregularly shaped as shown in FIG. **5-70**. Furthermore, the lower portion of the arms **7130** may be recessed to increase flexibility (e.g., see recessed portion **7131** shown in FIG. **5-71**).

In an embodiment, a rib **7140** may be provided to the base of the arms **7130** (as shown in FIGS. **5-69** to **5-74**). In an embodiment, the rib **7140** may be generally hemispherical or curved as shown in FIGS. **5-69**, **5-71** and **5-72**. In an alternative embodiment, the rib **7140** may be generally rectangular (or square) as shown in FIGS. **5-70** and **5-74**. In another embodiment, the rib **7140** may be raised from the surface of arms **7130** as shown in FIG. **5-73** (e.g., T-shaped). The rib **7140** prevents the air delivery tube from sliding erratically once engaged with tube retainer **7100**, meaning that the headgear and air delivery tube can be held in a secure position.

In an embodiment, the arms **7130** may have a locking mechanism **7135** that operates with a ball and clasp type joint (e.g., see FIGS. **5-72** to **5-75**, **5-77**, and **5-78**). As illustrated, the locking mechanism **7135** includes a ball **7136** on one of the arms **7130** and a clasp **7137** on the other of the arms **7130**. In use, the ball **7137** and clasp **7137** can be pushed together and interlocked to close the arms **7130** around the air delivery tube. In an embodiment, the clasp **7137** may have one or more teeth **7137.1** on its inner radius that are adapted to engage with respective grooves **7136.1** on the ball **7136** as shown in FIG. **5-75**. The teeth to grooves feature will further secure and retain the locking mechanism **7135** in its locking position.

In another embodiment, the upper ends of the arms **7130** may include a lead-in **7150** as shown in FIG. **5-76**. The lead-in **7150** enables easier insertion of the air delivery tube through the gap between the arms **7130**. The lead-in **7150** may also be combined with a locking mechanism **7135** as shown in FIGS. **5-77** and **5-78**. In FIG. **5-78**, ribbing **7151** may be provided to the under surface of each lead-in **7150**. Ribbing **7151** enables the user to obtain a better grip when pulling the arms **7130** outward to remove the air delivery tube or when disengaging the locking mechanism **7135**. In yet another embodiment, teeth **7152** may be provided to the inner surface of the lead-in **7150** to contact the air delivery tube and provide better stability of the air delivery tube, as shown in FIGS. **5-79** and **5-80**. The teeth **7152** may be generally square (as shown in FIG. **5-79**), may be generally round (as shown in FIG. **5-80**), may have other suitable shapes.

The inner radius of the arms **7130** may also be provided with one or more ribs **7131** as shown in FIG. **5-81**. In use, the ribs **7131** provide support for the air delivery tube in the lateral direction. There may be any suitable number of ribs **7131** (e.g., 2, 4, 7, or more) and these ribs may be spaced evenly or randomly. The ribs **7131** may also vary in size, e.g., the ribs may all be the same size or become longer to support different shaped tubes.

Tab

In the illustrated embodiments, each tube retainer **7100** has a tab **7160** at its base that is structured to engage with a keyhole **7060** provided to the buckle **7000**. FIGS. **5-68** to **5-86** show several embodiments of tab **7160**.

In an embodiment, the tab **7160** may be generally round as shown in FIG. **5-76**. In an alternative embodiment, the tab **7160** may assume other suitable shapes, e.g., cross-like shape as shown in FIG. **5-82**. In another form, the tab **7160** may have a fissure **7170** through its length (e.g., split configuration) as shown in FIG. **5-79**. In another embodiment, the tab **7160** may include multiple fissures **7170** (e.g., multiple prong arrangement). The fissure **7170** may be any suitable shape, e.g., square, circular or elliptical. The fissure **7170** is provided to add flexion in tab **7160** to allow for easier engagement and disengagement with the buckle keyhole **7060**. The flexion in tab **7160** also provides a snapping sound when the tab **7160** is locked in the buckle keyhole **7060**, which provides tactile feedback that the system is correctly aligned. In another embodiment, the tab **7160** may have a cut out **7161** through a portion of its length as shown in FIG. **5-86**. In embodiments, there may be one or more cut outs **7161** provided to the tab, e.g., 1, 2, 4, 7, or any other suitable number. The cut-out **7161** may be generally c-shaped or arcuate, or may have other suitable shapes. In use, the cut-out **7161** enables greater flexibility of the tab **7160**.

In yet another embodiment, the tab **7160** may have a lip **7165** extending from its distal end as shown in FIG. **5-76**. The lip **7165** is adapted to lock the tab **7160** in the buckle keyhole **7060** by an interference fit. In an embodiment, the lip **7165** may extend around the entire perimeter of the distal end of tab **7160** (e.g., as shown in FIGS. **5-76** and **5-85**). In an alternative embodiment, the lip **7165** may extend around a portion or portions of the distal end of the tab **7160** (e.g., as shown in FIG. **5-83**). In another embodiment, the depth and length of the lip **7165** may be varied. In an alternative embodiment, one or more finger tabs **7165.1** may be provided to the tab that extend upwards from the topside of the lip **7165** (as shown in FIG. **5-84**). In an embodiment, the finger tabs **7165.1** may be generally rectangular, round, triangular, or any other suitable shape. In use. the finger tabs **7165.1** allow fixed rotation of the tube retainer **7100** once engaged with the buckle **7000**.

In an embodiment, the tab **7160** may also have a joining ridge **7166** at its proximal end as shown in FIG. **5-76** (e.g., adjacent its interface with the arms **7130**). In an embodiment, the joining ridge **7166** may be generally round but may have other suitable shapes. The joining ridge **7166** is provided to ensure a snug fit of the tab **7160** with the buckle keyhole **7060** so as to avoid lateral movement of the tube retainer **7100** with respect to the buckle **7000**. In an alternative embodiment, one or more finger tabs **7166.1** may extend downwards from the underside of the joining ridge **7166** as shown in FIG. **5-85**. In an embodiment, the finger tabs **7166.1** may be generally rectangular, round, triangular, or any other suitable shape. In use, the finger tabs **7166.1** allow fixed rotation of the tube retainer **7100** once engaged with buckle **7000**.

Other alternatives to increase headgear flexibility to accommodate different sleep positions includes: integrate tubing into headgear through conduit system; and/or introduce an elbow that accommodates a wider range of movement through a ball and socket joint. The ball and socket joint elbow may also provide decoupling of forces due to shifts in tube position.

Other alternatives to increase decoupling of forces due to shifts in tube position include: provide a tube that has increased levels of flexibility in the axial directions; interrupt tube with highly flexible element (i.e., thin silicone element) below elbow; provide a tube that is constructed from an overall sifter material; and/or provide a tube that is constructed from an overall more lightweight material.

2.6 Other Aspects

Headgear Cost Reduction

To reduce the cost of the headgear, the headgear may incorporate one or more of the following: replace textile components with molded components; reduce part count for headgear; reduce materials used in headgear; reduce labor involved in assembling headgear; increase mechanization of assembly process; and/or new material cutting profile to reduce wastage.

FIGS. **11-1** and **11-2** illustrate an exemplary cutting profile for headgear straps to reduce wastage. In the illustrated embodiment, the headgear includes two strap configurations, i.e., one for the side strap **53** and one for the rear strap **57**. FIG. **11-1** illustrates a cutting profile for the generally boomerang shaped side straps **53**, and FIG. **11-2** illustrates a cutting profile for the generally straight rear strap **57**. In each embodiment, the straps are arranged side by side to reduce material wastage.

Reducing Headgear Presence

Alternative embodiments to reduce the perceived presence of headgear (e.g., headgear made to feel more minimal/lightweight, provide minimal skin contact, and provide low intrusion into the field of view to reduce the likelihood of claustrophobia) include: providing a completely elastic headgear strap design; reducing the overall amount of skin contact that the headgear has with the user; introducing a skin toned or transparent headgear (e.g., chameleon headgear); eliminating all hard plastic components such as buckles and yokes; introducing cotton as the skin contact material (e.g., cotton may be better on skin and may be more synonymous with clothing); using a cup or parachute material section to capture the crown (e.g., a net like section that may be made from cotton); reducing the overall material thickness of all parts of the headgear; using two or three thin (e.g., 1 mm) wire-style strips of nylon to connect the frame to the headgear body (e.g., this arrangement may accommodate fine adjustments and may have a very fine appearance on the user, and this arrangement may be incorporated into a net style headgear which would appear almost invisible amongst the user's hair); eliminating the headgear and replacing its function with balloon style pillows that inflate up against the walls of the nasal passage to hold the pillows in place; and/or using an internal mouth guard which has magnets incorporated into it that will hold the pillow and frame assembly up against the upper lip and in position to retain a good seal (e.g., this arrangement may be incorporated with a balloon style prong system to completely eliminate the headgear).

Headgear Usability

Alternative embodiments to reduce the number/complexity of adjustments to achieve a correct fit/good seal include: introducing a single piece headgear that is highly flexible and provides sufficient breathability; introducing a highly flexible net style headgear system to capture the crown; and/or eliminating buckles and introducing a headgear that uses a simpler series of adjustment mechanisms.

Alternative embodiments to improve the intuitiveness of headgear adjustment include: introducing a 3D shape headgear that provides an obvious visual cue as to the correct fitting of the headgear; positioning the adjustment mechanisms closer to the region influenced by the adjustments (e.g., seal region) such that adjustments are more intuitive; introducing Velcro tabs that provide a more intuitive method of adjustment; and/or utilizing large Velcro tab sections as rigidizing elements to replace headgear yokes.

Alternative embodiments to improve the "set and forget" functionality of headgear (e.g., no need to reset/readjust after removal of headgear) include: incorporating a highly flexible element at points on the headgear that allow stretching to be isolated to aid rapid removal/replacement of headgear; and/or increasing the flexibility of the nasal pillows to accommodate the rapid removal/replacement of headgear.

Alternative embodiments to reduce the overall number of headgear parts include: providing single part headgear (e.g., textile or molded headgear); introducing Velcro tabs rather than having separate buckles; over-molding/insert molding the seal rings into the yokes; making the seal ring and yoke a single part; and/or utilizing large Velcro tab sections as rigidizing elements to replace the headgear yokes.

Alternative embodiments to improve ease of assembly/disassembly include: reducing overall number of parts; incorporating features that prevent disassembly (e.g., one time assembly); improving intuitiveness of assembly and disassembly (e.g., through color coding or physical locators/indicators); reducing the overall number of "open ends" (e.g., eliminate back buckle); introducing 2-tone headgear (e.g., different color on the inside surface to the outside surface which may reduce incidents of incorrect assembly in manufacturing; eliminating seal rings; and/or providing one-way assembly of headgear through headgear buckles (e.g., restricted by geometry).

Alternative embodiments to improve ease of cleaning all surfaces include: reducing overall number of parts; making headgear suitable for thermal disinfection so that the interface does not have to be completely disassembled to disinfect; and/or eliminating textile headgear (e.g., replace textile headgear with an elastomeric or thermoplastic material that does not collect oil and moisture which may allow the headgear to be wiped down as with other components of the interface and may increase durability).

Alternative embodiments to increase the overall durability of headgear include: eliminating textile headgear (e.g., replace textile headgear with an elastomeric or thermoplastic material that does not collect oil and moisture which may allow the headgear to be wiped down as with other components of the interface and may increase durability); reducing the need for adjustment; reducing the overall number of parts (e.g., interfacing parts); and/or creating headgear straps out of a single material structure rather than a laminated one (e.g., foam only headgear straps).

Headgear Alternatives

FIGS. **12-1** to **12-26-2** illustrate headgear alternatives for the patient interface. It should be appreciated that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

Mechanical Hinge

FIGS. **12-17** to **12-18-2** illustrate headgear with mechanical hinges. Such hinges are structured to reduce or eliminate the influence of lateral forces on the seal region. In addition, lateral hinges may help to reduce or eliminate marking on the cheeks as the hinges allow accommodation of users of varying facial widths and takes pressure off of the face.

In FIG. **12-17**, the headgear includes headgear straps **3653** that cup the crown of the patient's head (e.g., similar to that shown in WO 2006/130903, which is incorporated herein by reference in its entirety), and yokes **3655** provided between the headgear straps **3653** and the nasal prong assembly. As illustrated, a lateral hinge **3695** is provided to an intermediate portion of the yoke **3655**, e.g., offset to cheek region, to allow lateral movement of the yoke **3655** in use. A cheek pad **3690** (e.g., high friction silicone cheek pad) is provided to the yoke **3655** adjacent the hinge **3695** to support the hinge **3695** in a position off the patient's face. In an embodiment, the cheek pad **3690** may be comolded or insert molded to the yoke **3655**. Also, the hinge **3695** may provide a quick-release function so that the hinge **3695** may be easily disconnected and allow quick removal of the headgear. The combination of the headgear strap arrangement and high friction silicone cheek pads may provide high levels of overall stability for the headgear.

In FIG. **12-18-1**, a lateral hinge **3795** is provided to either end portion of the yoke **3755** (e.g., at the nasal prong assembly **3720** and/or at the headgear straps **3753**) to allow lateral movement of the yoke **3755** in use. In the illustrated embodiment, the hinge **3795** is provided between the nasal prong assembly **3720** and the proximal end of the yoke **3755**. A pad (not visible) is provided along the yoke **3755** to support the hinge **3795** in a position off the patient's face. As shown in FIG. **12-18-2**, the end of the frame of the nasal prong assembly **3720** provides dimples **3796** and an aperture **3797** for engaging an elbow or end plug. The proximal end of the yoke **3755** provides spaced apart arms **3798** that snap into respective dimples **3796** on the end of frame to form the lateral hinge **3795**. Also, the hinge **3795** may provide a quick-release function so that the hinge **3795** may be easily disconnected and allow quick removal of the headgear.

Headgear Without "Dog Ear" Style Straps

FIGS. **12-22** to **12-25-2** illustrate headgear without "dog ear" style straps.

In FIG. **12-22**, the headgear includes side strap portions **4153** (e.g., constructed of Breathoprene), headgear yoke **4155** provided to the side strap portions, and upper and lower connecting strap portions **4157**(U), **4157**(L) structured to connect the side strap portions. As illustrated, molded plastic crimps **4196** are positioned on ends of the side strap portions to engage respective ends of the connecting strap portions **4157**(U), **4157**(L) and allow length adjustment. The connecting strap portions **4157**(U), **4157**(L) may include a highly flexible elastic element to accommodate easy fitting/removal of the headgear. Also, the plastic crimps **4196** are positioned to avoid pressing into the patient's head in the most likely sleep positions, e.g., back and side of the head.

In FIGS. **12-23-1** and **12-23-2**, the headgear includes side strap portions **4253** (e.g., constructed of Breathoprene), and upper and lower connecting strap portions **4257**(U), **4257**(L) structured to connect the side strap portions. As illustrated, molded plastic/silicone crimps **4296** are positioned to engage the connecting strap portions and allow length adjustment. The connecting strap portions **4257**(U), **4257**(L) may include a highly flexible elastic element to accommodate easy fitting/removal of the headgear. Also, the molded plastic/silicone crimps **4296** may be positioned anywhere along the connecting strap portions to avoid the patient's sleeping position, e.g., so patient does not lie on crimps. FIG. **12-23-1** illustrates one crimp **4296** provided to connect respective connecting strap portions **4257**(U), **4257**(L), and FIG. **12-23-2** illustrates two crimps **4296** provided to connect respective connecting strap portions **4257**(U), **4257**(L). In an embodiment, the crimp may be in the form of a hinged c-clip that may be opened to adjust and closed to crimp, e.g., such as that shown in FIG. **12-25-2**.

In FIG. **12-24-1**, the headgear includes side strap portions **4353** (e.g., constructed of Breathoprene), and upper and lower connecting strap portions **4357**(U), **4357**(L) structured to connect the side strap portions. As illustrated, each end of a connecting strap portion includes a two-part clip **4396** (e.g., constructed of plastic) adapted to engage a selected one of incremental holes **4397** provided along the side strap portions. As shown in FIGS. **12-24-2** and **12-14-3**, each two-part clip **4396** includes a top section **4396(1)** that protrudes through the selected hole **4397** in the strap portion and a bottom section **4396(2)** that snaps onto the top section **4396(1)** (e.g., via prongs provided on the top section) to fasten the clip in place. The connecting strap portion **4357**(U), **4357**(L) may be constructed of a highly flexible silicone/elastomeric material to accommodate easy fitting/removal of the headgear.

In FIG. **12-25-1**, the headgear includes side strap portions **4453** (e.g., constructed of Breathoprene), and upper and lower connecting strap portions **4457**(U), **4457**(L) structured to connect the side strap portions. As illustrated, a single piece living hinge component **4496** (e.g., molded of plastic) is positioned on ends of the side strap portions to engage respective ends of the connecting strap portions and allow length adjustment. As shown in FIG. **12-25-2**, the living hinge component **4496** provides first and second portions **4496**(**1**), **4496**(**2**) and a groove **4496**(**3**) in each portion to receive the strap portions and crimp or clamp the strap portions in place. The connecting strap portions **4457**(U), **4457**(L) may include a highly flexible elastic element to accommodate easy fitting/removal of the headgear (e.g., highly flexible elastic element can elastically deform to allow headgear removal).

Incremental Lateral Adjustment

In FIG. **12-26-1**, the headgear includes headgear straps **4553** that cup the crown of the patient's head, and yokes **4555** (e.g., silicone/molded plastic yokes) provided between the headgear straps **4553** and the nasal prong assembly **4520**. In this embodiment, each yoke **4555** may be adjusted by a "cam" style lock or ratchet mechanism **4575** that is incorporated into a molded plastic section **4576** on the side of the headgear straps **4553**. As shown in FIG. **12-26-2**, the molded plastic section **4576** is structured to receive a end portion of the yoke **4555** therethrough, and the plastic section **4576** includes a locking arrangement to lock the end portion of the yoke in place. The locking arrangement includes a simple release button **4577** to release the yoke **4555**. Also, the end portion of the yoke **4555** may have subtle ridges or teeth to provide tactile feedback to the user on strap tension adjustment.

This embodiment provides increased levels of usability (e.g., particularly during fitting and adjustment) for intuitive features such as single piece 3D shaped headgear and lateral headgear tension adjustments.

Alternative Headgear Embodiments to Improve Stability

Headgear stability may be improved by eliminating dislodging of the headgear on the head and/or capturing the crown region of the head.

Exemplary headgear embodiments for improving stability include: provide additional support around the head through a secondary strap which runs under the ears; provide additional support around the head through capturing the crown region with different headgear geometry; provide additional support around the head through one size fits all crown cap or a single piece of material that sits over the crown of the head (e.g., may be perforated to allow breathing or take the form of a netted section of material, may also take the form of a two strap parachute style headgear); increase stability of headgear through the incorporation of a high friction material such as textured rubber or textile (e.g., Velcro); increase stability through use of more silicone parts against the skin as this has a high friction coefficient; and/or alter the way in which the headgear captures the crown, e.g., sits further forward on the head and has a strap that runs along one plane to capture the crown (this aids in clearance of the ear lobes, etc.).

Headgear Properties

Each headgear embodiment described above may include one or more features to increase headgear fitting range, improve headgear comfort, reduce headgear cost, improve headgear aesthetics, and/or increase prominence of branding.

For example, headgear embodiments may increase overall comfort by eliminating potential ergonomic hotspots, eliminating sources of marking/irritation, creating a lightweight feel, and/or maintaining high levels of material breathability. Headgear embodiments may be designed in a manner that deviates from a "medical product" aesthetic but reflects a "lifestyle product" aesthetic, and creates a higher quality looking product overall. Also, headgear embodiments may incorporate and support more prominent branding through optimal branding locations and increased differentiation of branding from the surrounding material.

Additional Embodiments

Additional embodiments may be generated by combining one or more features of any one of the above-described embodiments with one or more features of the other of the above-described embodiments. Such additional embodiments may include one or more of the following features:

Stability

Captures the crown region of the head sufficiently;

Decouples headgear forces well;

Accommodates different sleeping positions;

Good stability on the face (hugs the face and uses the structure of the face for stability); and/or

Good stability of the headgear on the head (no slipping around).

Comfort

Reduce or eliminate irritation/marking on cheeks (swoosh marks);

Reduce or eliminate irritation caused by buckle;

Reduce or eliminate marking/irritation occurring on the upper ear lobes; and/or

Good tactile quality (soft feel wherever possible).

Usability

Intuitive fitting;

Simple and quick adjustment;

Minimal number of adjustments to achieve a good fit;

Ability to make precision adjustments to maintain a good seal;

Set and forget functionality; and/or

Minimal number of parts.

Unobtrusiveness

Low perceived presence by the user (avoids the user's line of sight);

Minimal overall size/visual impact of interface when on user; and/or

Minimal skin contact and low likelihood of overheating the patient or claustrophobia.

Aesthetics and Branding

Lifestyle product aesthetic ("non medical");

Improved overall function through aesthetics (e.g., visual cues for positioning and adjustment);

"High comfort" visual appearance;

Aesthetically pleasing and high quality user-product relationship building features (e.g., customizable features, colors, etc.);

Prominence of branding; and/or

High quality of branding.

Cleaning/Maintenance

Ease of assembly/disassembly (e.g., familiarity);

Ease of cleaning all surfaces (e.g., includes areas that do not become clogged or trap dirt); and/or

Overall durability.

3 Connection with Air Supply

Elbow

As shown in FIGS. **18-1** to **18-7**, the elbow **5040** (e.g., constructed of a relatively hard plastic material such as polypropylene, Hytrel, HTPC) includes a first portion **5042** provided to the frame **5030** and a second portion **5044** provided to a short tube **5070** (e.g., see FIGS. **14-1** and **17**) adapted to be connected to an air delivery tube.

The elbow **5040** is structured to provide easy assembly/disassembly to the frame, rotation with respect to the frame with acceptable level of torque, seal, and venting. In addition, the elbow directs air into the patient interface without significant flow restrictions.

In an embodiment of the elbow (see FIGS. **18-1** to **18-7**), D**1** may be about 15-20 mm, e.g., 17.99 mm, D**2** may be about 10-20 mm, e.g., 15 mm, D**3** may be about 5-10 mm, e.g., 7.8 mm, D**4** may be about 5-15 mm, e.g., 9.6 mm, and D**5** may be about 10-15 mm, e.g., 13.5 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

As illustrated, the second portion **5044** tapers to a smaller internal diameter at D5 (e.g., about 13.5 mm), e.g., for sealing the lip **5075.1** of the tube against surface **5048** (e.g., see FIG. **17**). Moreover, gas passes from a smaller diameter at D5 (e.g., about 13.5 mm) to a larger diameter at D2 (e.g., about 15 mm), which reduces the pressure drop through the elbow to maintain a sufficient impedance level.

In the illustrated embodiment, the first portion **5042** is angled about 90° with respect to the second portion **5044**. This arrangement provides a low profile in use, e.g., 90° elbow and attached tubing does not stick outwardly when rotated, reduces mask size. In addition, the 90° elbow provides a quieter venting arrangement and is easier to tool/manufacture with a 90° flat blank at the surface for the vent hole pins. However, the first and second portions of the elbow may have other suitable angles with respect to one another, e.g., 120°. In an alternative embodiment, the elbow may include one or more baffles along its interior.

Frame Attachment

The first portion **5042** of the elbow **5040** includes a tapered retaining portion **5043.1**, a circumferential flange **5043.2**, and a circumferential rib **5043.3** between the retaining portion **5043.1** and the flange **5043.2**. The first portion **5042** is engageable with the tube portion **5035** of the frame **5030**. The tube portion **5035** include an inwardly facing circumferential rib **5035.1** at an inner end and an inwardly facing circumferential sealing lip **5035.2** at an outer end (e.g., see FIGS. **15-10** and **15-11**).

The first portion **5042** of the elbow **5040** is inserted into the tube portion **5035** of the frame **5030** and the retaining portion **5043.1** engages the rib **5035.1** with a snap-fit (relatively hard elbow snaps into relatively soft frame). That is, the retaining portion **5043.1** deforms and compresses the rib **5035.1** inwardly until the retaining portion **5043.1** reaches its operative position in which the rib **5035.1** springs back to original form, as shown in FIG. **17**. As illustrated, the sealing lip **5035.2** of the frame **5030** provides a seal around the perimeter of the first portion **5042** and/or the sloped surface of portion **5043.2** of the elbow **5040**. Because the frame provides a relatively soft part to engage the relatively hard elbow, no additional seal ring is needed to seal between the frame and elbow.

The circumferential flange **5043.2** and circumferential rib **5043.3** (rib **5043.3** may be optional) provided to the elbow **5040** help prevent rotation of the elbow **5040** relative to the frame (e.g., prevents rocking or wiggle and keeps elbow and frame concentric). In an embodiment, the circumferential rib **5043.3** may be spaced apart ribs (rather than continuous) to reduce friction.

In the illustrated embodiment, a small clearance may be provided between the circumferential flange **5043.2** and the edge of the opening into the internal volume of the frame, e.g., only contact points are the sealing lip **5035.2** with the elbow and the retaining portion **5043.1** with the frame. Thus, the insertion length of the elbow into the frame is about the length of D**4** (e.g., about 9-11 mm (e.g., 9.6 mm)), which provides sufficient length to securely retain the elbow to the frame. In addition, the elbow does not engage the frame along its entire length, so less friction is provided between the elbow and the frame. In an embodiment, the ratio of the insertion length (D**4**) to the related elbow diameter (D**2**) may be about 50-75%, e.g., 9.6/15 or about 65%.

Also, the sealing lip **5035.1** is angled towards the inlet of the frame opening and engages a lower end of the circumferential flange **5043.2**, as shown in FIG. **17**. This arrangement allows the sealing lip **5035.1** to maintain a seal with the elbow **5040**, e.g., when tube drag or other force applied to elbow causes bending movement of the first portion with respect to the frame. For example, as the elbow pivots with respect to the frame due to an external force, the sealing lip **5035.1** resiliently maintains contact with the tapered surface of the circumferential flange **5043.2**.

However, it should be appreciated that the elbow **5040** may be attached to the frame **5030** in other suitable arrangements, e.g., ball joint.

FIGS. **18-9-1** to **18-18-3** illustrate elbow to frame attachments according to alternative embodiments of the present invention.

FIGS. **18-9-1** to **18-9-3** illustrate an elbow **7340** attached to the frame **7330** by a ball and socket type joint. In the illustrated embodiment, the ball **7345** is provided to the elbow **7340** and the socket **7335** is provided to the frame **7330**. However, it should be appreciated that the opposite arrangement is possible, i.e., socket on elbow and ball on frame.

As illustrated, the socket **7335** on frame **7330** provides a generally rounded inwardly facing surface, and the ball **7345** on elbow **7340** has a generally rounded or spherical outwardly facing surface adapted to engage the socket **7335** with an interference fit.

Also, the frame **7330** provides a channel **7333** structured to retain the nasal prong assembly, and the main body of the elbow **7340** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7328** for gas washout. In the illustrated embodiment, the vent holes **7328** are arranged in a generally circular or arcuate manner. However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

FIGS. **18-10-1** to **18-10-3** illustrate a relatively soft elbow **7440** (e.g., relatively semi-rigid or soft plastic material (e.g., hard silicone (e.g., 30-80 shore A silicone))) attached to a frame **7430**. As illustrated, the frame **7430** includes a tube portion **7435** with a rib **7435.1** and an inwardly facing sealing surface **7435.2**. The elbow **7440** includes a retaining portion **7443.1** adapted to engage the rib **7435.1** (e.g., with a snap fit) and a sealing end portion **7443.2** adapted to engage the sealing surface **7435.2** to provide a seal. Also, the elbow **7440** includes a flange **7443.3** adapted to engage the end face of the tube portion **7435**. Because the elbow provides a relatively soft part to engage the frame, no additional seal ring is provided to seal between the frame and elbow.

Also, the frame **7430** provides a channel **7433** structured to retain the nasal prong assembly, and the main body of the elbow **7440** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7428** for gas washout. In the illustrated embodiment, the vent holes **7428** are arranged in a generally circular or arcuate manner. However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

FIGS. **18-11-1** to **18-11-3** illustrate a relatively soft elbow **7540** attached to a frame **7530** and to a relatively hard swivel **7560**. As illustrated, the frame **7530** includes a tube portion **7535** with a rib **7535.1** and an inwardly facing sealing surface **7535.2**. One end of the elbow **7540** includes a retaining portion **7543.1** adapted to engage the rib **7535.1** (e.g., with a snap fit) and a sealing end portion **7543.2** adapted to engage the sealing surface **7535.2** to provide a seal. Also, the elbow **7540** includes a flange **7543.3** adapted to engage the end face of the tube portion **7535**.

The swivel **7560** includes a rib **7565.1** and an inwardly facing sealing surface **7565.2**. The other end of the elbow **7540** includes a retaining portion **7545.1** adapted to engage the rib **7565.1** (e.g., with a snap fit) and a sealing end portion **7545.2** adapted to engage the sealing surface **7565.2** to provide a seal. Also, the elbow **7540** includes a flange **7545.3** adapted to engage the end face of the swivel **7560**.

Because the elbow provides a relatively soft part to engage the frame and swivel, no additional seal ring is provided to seal between the frame and elbow or between the swivel and elbow.

Also, the frame **7530** provides a channel **7533** structured to retain the nasal prong assembly, and the main body of the elbow **7540** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7528** for gas washout. In the illustrated embodiment, the vent holes **7528** are arranged in a generally circular manner (e.g., concentric circles). However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

FIGS. **18-12-1** to **18-12-3** illustrate a relatively hard elbow **7640** with a seal ring attached to a frame **7630**. As illustrated, the frame **7630** includes a tube portion **7635** with a shoulder **7635.1**. The elbow **7640** includes a retaining portion **7643.1** adapted to engage the shoulder **7635.1** (e.g., with a snap fit). A slot **7641** is provided to opposing sides of the elbow **7640** to facilitate deflection during its snap-fit attachment.

Also, the frame **7630** provides a channel **7633** structured to retain the nasal prong assembly, and the main body of the elbow **7640** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7628** for gas washout. In the illustrated embodiment, the vent holes **7628** are arranged in a generally circular or arcuate manner. However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

FIGS. **18-13-1** to **18-13-3** illustrate a relatively soft elbow **7740** attached to a frame **7730** with a relatively large frame bore. As illustrated, the frame **7730** includes a tube portion **7735** with a rib **7735.1**. The elbow **7740** includes a retaining portion **7743.1** adapted to engage the rib **7735.1** (e.g., with a snap fit). Also, the elbow **7740** includes a flange **7743.3** adapted to engage the end face of the tube portion **7735**.

Also, the frame **7730** provides a channel **7733** structured to retain the nasal prong assembly, and the main body of the elbow **7740** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7728** for gas washout. In the illustrated embodiment, the vent holes **7728** are arranged in offset rows (e.g., six offset rows). However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

In addition, the elbow **7740** includes a baffle **7750** that is arranged to divide the upper arm of the elbow into an air delivery passage and an exhaust passage. As illustrated, the baffle has a wavy or w-shaped configuration. However, other baffle shapes are possible.

FIGS. **18-14-1** to **18-14-3** illustrate a relatively soft elbow **7840** attached to a frame **7830** with a large frame bore. As illustrated, the frame **7830** includes a tube portion **7835** with a rib **7835.1**. The elbow **7840** includes a retaining portion **7843.1** adapted to engage the rib **7835.1** (e.g., with a snap fit). Also, the elbow **7840** includes a flange **7843.3** adapted to engage the end face of the tube portion **7835**.

Also, the frame **7830** provides a channel **7833** structured to retain the nasal prong assembly, and the main body of the elbow **7840** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7828** for gas washout. In the illustrated embodiment, the vent holes **7828** are arranged in offset rows (e.g., three offset rows). However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

In addition, the elbow **7840** includes a baffle **7850** that is arranged to divide the upper arm of the elbow into an air delivery passage and an exhaust passage. As illustrated, the baffle has a generally flat or planar configuration. However, other baffle shapes are possible.

FIGS. **18-15-1** to **18-15-3** illustrate an elbow **7940** attached to a frame **7930** with a large frame bore. As illustrated, the frame **7930** includes a tube portion **7935** with a rib **7935.1**. The elbow **7940** includes a retaining portion **7943.1** adapted to engage the rib **7935.1** (e.g., with a snap fit). Also, the elbow **7940** includes a flange **7943.3** adapted to engage the end face of the tube portion **7935**.

Also, the frame **7930** provides a channel **7933** structured to retain the nasal prong assembly, and the main body of the elbow **7940** includes a relatively flat portion for a vent arrangement. The vent arrangement includes a plurality of vent holes **7928** for gas washout. In the illustrated embodiment, the vent holes **7928** are arranged in an arc and each vent hole includes a generally oval or capsule shape. However, other suitable hole arrangements, hole numbers, and/or hole shapes on the elbow are possible.

In addition, the elbow **7940** includes a baffle **7950** that is arranged to divide the upper arm of the elbow into an air delivery passage and an exhaust passage. As illustrated, the baffle has a generally inverse U-shaped configuration. However, other baffle shapes are possible.

FIGS. **18-16-1** to **18-16-3** illustrate an elbow to frame attachment similar to that shown in FIGS. **18-15-1** to **18-15-3** and indicated with similar reference numerals. In contrast, the vent holes **7928** are arranged in an arc with a larger radius of curvature, and the baffle **7950** has a larger radius of curvature (i.e., similar to the vent hole arc).

FIGS. **18-17-1** to **18-17-3** illustrate an elbow to frame attachment similar to that shown in FIGS. **18-15-1** to **18-15-3** and indicated with similar reference numerals. In contrast, each vent hole **7928** has a general U-shape and the vent holes are arranged on a flat portion that is recessed with respect to the exterior surface of the elbow. In addition, the baffle **7950** has a generally U-shaped configuration.

FIGS. **18-18-1** to **18-18-3** illustrate an elbow to frame attachment similar to that shown in FIGS. **18-15-1** to **18-15-3** and indicated with similar reference numerals. In contrast, the vent holes **7928** are arranged in offset columns and arranged on a flat portion that is recessed with respect to the exterior surface of the elbow. In addition, the baffle **7950** has a generally U-shaped configuration.

Vent Arrangement

A vent arrangement **5045** is positioned on a relatively flat portion of the elbow **5040**. As illustrated, the relatively flat portion has a generally circular shape.

In the illustrated embodiment, the vent arrangement **5045** includes a plurality of holes **5047** arranged in concentric rings, e.g., three concentric rings R**1**, R**2**, R**3**. As shown in FIGS. **18-1**, **18-2**, and **18-7**, the center ring R**1** includes 3-10 holes, e.g., 6 holes, the intermediate ring R**2** includes 5-30 holes, e.g., 14 holes, and the outside ring R**3** includes 5-50 holes, e.g., 22 holes.

In the illustrated embodiment, each hole **5047** may have a generally part conic shape, including opposed walls that converge from a larger (inside) diameter to a smaller (outside) diameter, as viewed in the direction of exhausted gas (see FIGS. **18-5** and **18-6**). In an embodiment, the maximum length of each hole **5047** may be about 2.5 mm, and the smaller outside diameter may be about 0.7 mm with a 5° draft angle.

However, it should be appreciated that the vent arrangement **5045** may include other suitable hole arrangements, hole numbers, and/or hole shapes.

Also, as shown in FIGS. **18-4**, **18-5**, and **18-7**, the elbow provides rounded edges along its interior surface in order to reduce noise at the corners of the elbow. Such arrangement may result in the vent holes of the outside ring R**3** being longer than the vent holes of the center and intermediate rings R**1**, R**2** (e.g., see FIG. **18-6**).

Elbow with Alternative Vent Arrangement

FIGS. **18-8-1** to **18-8-15** illustrate an elbow **5740** (e.g., constructed of polypropylene) according to another embodiment of the present invention. As illustrated, the first portion **5742** is angled about 90-130°, e.g., 105° with respect to the second portion **5744**. In addition, the first and second end portions **5742**, **5744** provide an alternative structure for engaging the frame and short tube respectively.

The vent arrangement **5745** is positioned on a relatively flat portion of the elbow **5740** and includes a plurality of holes **5747** arranged in offset rows. As shown in FIGS. **18-8-5** and **18-8-8**, the arrangement **5745** may include 1-15 rows, e.g., 9 rows, with each row including 3-10 holes, e.g., 5, 6, or 7 holes. In an embodiment, the vent arrangement may include 40-70 total holes, e.g., 53 holes.

In the illustrated embodiment, each hole **5747** may have a generally part conic shape, including opposed walls that converge from a larger (inside) diameter to a smaller (outside) diameter, as viewed in the direction of exhausted gas (see FIGS. **18-8-11**, **18-8-13**, and **18-8-15**). In an embodiment, the smaller outside diameter D**1** may be about 0.6 mm with a draft angle D**2** of about 5°. Edges of the larger (inside) diameter may be rounded, e.g., inlet radius D**4** about 0.25-0.5 mm (e.g., 0.34 mm).

In this embodiment, each vent hole **5747** includes a diameter (about 0.6 mm) that is smaller than the diameter of each vent hole for ResMed's Swift II mask (about 0.7 mm). Thus, in comparison to ResMed's Swift II mask, each vent hole **5747** provides a smaller venting area (venting area=number of holes×area of each hole), less vent flow, and a smaller pitch (distance between holes).

As shown in FIGS. **18-8-10**, **18-8-12**, and **18-8-14**, tooling for the elbow **5740** provides a smooth inner path, e.g., the elbow includes rounded edges along its interior surface, e.g., in order to reduce noise. Such arrangement may result in outer vent holes being longer than inner vent holes, e.g., length D**5** may be about 2-3 mm (e.g., 2.47 mm) and length D**6** may be about 1.5-2.5 mm (e.g., 1.81 mm) as shown in FIG. **18-8-13**. In FIG. **18-8-11**, the vent holes along the vertical axis have a length D**3** of about 1.5-2.5 mm, e.g., 1.7 mm.

However, it should be appreciated that the vent arrangement **5745** may include other suitable hole arrangements, hole numbers, hole sizes, and/or hole shapes.

The elbow **5740** is structured to provide an interface between the frame and the short tube assembly (e.g., see FIGS. **20-5-1** to **20-5-6**). Venting of the mask system is provided by the array of small vent holes **5747** located in the elbow with a constant exhaust direction regardless of the elbow rotation position. The elbow decouples twisting forces from tubing to the frame by providing a 360 degree rotation with the frame. This rotation (in conjunction with the optional tube retainer) also allows the user to position the short tube and air delivery tubing in a preferred location for sleeping. The elbow to frame interface ensures that the elbow remains connected during use and allows the user to quickly assemble and disassemble tubing during the night and for easy cleaning.

The elbow includes one or more of the following functions: to provide a means of attaching tubing to the frame; to provide adequate area for a vent (due to limited space on the rest of the patient interface); to provide a total vent flow (in conjunction with the rest of the mask system) for safe use and flow generator compatibility; to provide an impedance (in conjunction with the rest of the mask system) within specification of ResMed's "Mirage" flow generator curve setting; to provide adequate CO_2 washout performance (in conjunction with the rest of the mask system); to provide adjustment of the tube position through 360 degree rotation; to provide a system of decoupling tube drag forces through rotation and/or swiveling actions; to provide easy assembly and disassembly with the mask; to provide adequate vent noise performance; to provide a vent direction that does not adversely affect the comfort of the patient or bed partner; to allow the user to easily clean the mask; to be unobtrusive and both visually and physically minimal in order to avoid the user feeling stifled or claustrophobic; and/or to be aesthetically pleasing and reflect high quality and style.

In an embodiment, the total flow specification for the patient interface of FIGS. **22-23-1** to **22-23-6** may be lower than the flow specification for ResMed's Swift II mask (e.g., minimum flow curve at 4 cmH2O to 20 cmH2O about 75% of Swift II nominal flow curve). The advantages of having a lower flow specification are reduced mask noise and reduced discomfort of jetting air inside the user's nose. In an embodiment, the length of the elbow inlet is sufficiently long to provide time for the flow to become laminar.

In the illustrated embodiment, the vent arrangement **5745** is located on the elbow **5740**. Alternatively, vents may be located at other suitable locations, e.g., on the frame, short tube, etc. In the illustrated embodiment, the vent design consists of an array of 53 holes of nominal diameter of 0.6 mm to provide adequate vent flow.

Features of the vent arrangement will now be described in greater detail. The vent pin blankoff provides a flat surface with about 75° blankoff. The elbow angle of 105° improves aesthetics and optimizes range of tubing positioning. The 105° elbow may also be quieter than a 120° elbow, for example. The flat surface for blankoff minimizes tooling risk, tool life/maintenance and flash.

The smaller vent hole size of Ø0.6 mm produces less noise and provides acceptable CO_2 performance with humidification maintained.

The vent hole draft (i.e., converging vent hole with 5° included draft) produce less noise.

The vent hole inlet radius of about 0.34 mm is larger (than ResMed's Swift II, about 0.25 mm) for less noise (e.g., maximum possible between holes).

The vent hole length may range from about 1.7 mm for inner holes to 2.5 mm for outer holes. A longer vent hole length is provided for less noise. The hole length varies, e.g., due to the curvature of the elbow, e.g., curvature provided for a smoother internal wall transition between the inlet and outlet which produces less noise.

As shown in FIG. **18-8-8**, the vent hole spacing includes D**7** of about 1.45 mm and D**8** of about 0.70 mm. The spacing between centers of about 1.45 mm corresponds to a minimum distance of approximately 0.7 mm between the tangency lines of the inlet radii, e.g., for tooling.

In an embodiment, the vent hole diameter, draft, inlet radius, length and spacing may be sized to fit in required space.

The internal elbow geometry provides an internal wall transition between the inlet and outlet that is relatively smooth. The smoother internal wall transition between the inlet and outlet produces less noise. As illustrated, the internal curvature is gradual while still maintaining an acceptable hole length for the outer holes due to the flat blank-off surface area.

The low mask noise of the patient interface may be achieved through one or more of the following features: lower flow specification (reduced flow means reduced noise); smaller vent hole diameter of Ø0.6 mm; increased vent hole length (for the outer holes) and larger inlet radius; elbow internal transition between inlet and outlet as gradual as possible; close spacing (high concentration) of vent holes leads to interaction between adjacent jets that reduces the noise; negligible leak in the rest of the patient interface which contributes to overall mask noise.

In an embodiment, the vent arrangement has a sound power of about 25 dBA (e.g., also due to the lower flow at the same pressure), which is significantly quieter than vents known in the art (e.g., ResMed's Swift II (28-29 dBA), Opus (31 dBA), OptiLife (34 dBA)).

As shown in FIG. **18-8-16**, the vent direction of the elbow **5740** is in the same direction as ResMed's Swift II mask (indicated by darker portion S**2**). The vent direction does not change with elbow rotation but is fixed in an axial direction. The 30 degree angle between the nasal prong assembly to frame interface and the prong to patient interface enables a vent direction equivalent to ResMed's Swift II mask to be achieved. Also, minor adjustments to the vent direction are possible by adjusting the yoke-to-frame orientation (the prong to patient seal can be maintained due to the flexibility in the nasal prong assembly).

The smaller vent hole diameter and the lower flow specification assists in minimizing jetting. Also, because the vent exhausts in a narrow beam, the jetting is confined to a smaller area and therefore potentially less likely to affect (or more easily managed by) the patient or bed partner.

The elbow design has been structured to suit the impedance requirements of the ResMed's "Mirage" flow curve. Matching the impedance characteristics in this way assists with ensuring compatibility with ResMed flow generators. However, it should be appreciated that the elbow may be used with other suitable flow generators.

FIG. **18-8-16** shows the elbow **5740** attached to the frame **6030** and nasal prong assembly **6020** described above. In the illustrated embodiment, the elbow to frame interface is a continuous annular snap fit between a polypropylene elbow and a silicone frame (70-75 Shore A durometer). This hard-to-soft type interface has a number of advantages with respect to the elbow-to-frame interface as detailed below.

When the elbow is assembled to the frame a thin silicone lip **6035.2** (thickness of 0.3 to 0.4 mm or less) is deflected creating an interference seal with the elbow sealing surface **5741**. The amount of interference is determined by both the axial stackup to the retention feature and the diametrical stackup. This interface effectively provides a zero leak interface under static operating conditions. The amount of interference has been designed to accommodate some tube drag.

The retention of the elbow to the frame is important to ensure that the short tube assembly does not inadvertently disconnect during use. A 10N tube drag load was considered to be sufficient retention force in all directions, e.g., at this force the mask seal to the patient is broken and likely to be completely clear of the face. The retention of the elbow is provided by a snap engagement of 0.7 mm all around the circumference. A 60 degree return angle A**1** on the elbow barb **5743.1** was implemented to assist disassembly by the user while maintaining sufficient retention.

Assembly and disassembly should be easy enough to be performed by a typical user with limited dexterity considering the small size of the parts. Assembly of the elbow to the frame is assisted with a 30 degrees insertion angle A**2** on the elbow barb **5743.1**. The intent was to have an axial assembly force under about 40N. Subjectively assembly is actually easier as the user is more likely to manipulate the elbow into position with some angle or twist and this requires less force. Elbow disassembly is linked with elbow retention however disassembly is realistically easier than the retention force as the user can peel the elbow out with much less force.

The elbow can rotate 360 degrees within the frame to provide flexibility in tube positions and decouple tube drag forces during sleep movement. Due to the hard-to-soft interference for sealing of the elbow to frame, some rotational resistance may be provided. Some resistance may be preferable over freely rotating as the tube can be located in a certain direction without it inadvertently swinging around and disturbing the wearer. Factors influencing the rotation torque include the sealing lip interference, the sealing lip thickness, and/or the silicone frame hardness.

Sufficient clearance elsewhere in the interface (e.g., between the elbow flange **5749** and frame **6030**) was ensured across tolerance ranges to ensure minimal contact and torque contribution. Clearance is controlled to some extent to minimize movement of the elbow within the frame that may lead to leakage under a tube drag load.

In an embodiment, the elbow rotation torque specification is less than 30Nmm and subjectively is considered to be acceptable if the short tube can rotate under its own weight.

FIG. **18-8-17** shows the interface between the elbow **5740** and the short tube **5770**, e.g., barbed, friction-type fit. The short tube material, e.g., made of Hytrel 5556, provides greater flexibility and durability and has a much higher thermal resistance enabling thermal disinfection at higher temperatures. The elbow/short tube interface may have other suitable arrangements, e.g., snap fit, swivel fit, etc.

The 105 degree angle elbow includes one or more of the following advantages: reduces the chance of the short tube impacting on the patient's chest while ensuring that the tube can be angled back far enough to route the tubing over the head; less noise; less obtrusive.

Wall thickness variation of the elbow was minimized however, some thicker wall sections were implemented to improve the aesthetics and unobtrusiveness of the elbow. The circular groove in the elbow flange **5749** was implemented to remove material bulk from this area of the elbow, improve molding quality, and/or dimensional control.

Short Tube and Swivel

The short tube **5070** is adapted to interconnect the patient interface with a standard air delivery tube (e.g., 22 mm tube). As shown in FIGS. **14-1** and **20-1**, the short tube **5070** includes a tube portion **5072** and end fittings **5074** provided to respective ends of the tube portion **5072**. The end fittings **5074** include the same structure, with one of the end fittings **5074** attachable to the second portion of the elbow **5040** and the other of the end fittings attachable to a swivel **5090** adapted to be connected to an air delivery tube. Such arrangement facilitates assembly and disassembly (e.g., for cleaning, disinfecting, etc.), provides a seal to reduce leak, and provides a limited number of parts to reduce assembly/disassembly steps.

The tube portion **5072** (e.g., 13-15 mm inner diameter (e.g., 13.5 mm inner diameter)) may have a reduced length (e.g., 30-40 mm (e.g., 35 mm)) to reduce impedance. Also, the width, height, pitch, and/or helical rib of the tube portion **5072** may be adjusted to adjust the flexibility of the short tube. For example, the size of the pitch of the helix around the tube portion may be adjusted to adjust the flexibility.

End Fittings

Each end fitting **5074** (e.g., constructed of a semi-rigid material such as TPE, silicone) may be integrally formed in one piece with the tube portion **5072** (e.g., constructed of a hard plastic material (e.g., 45-55 shore D hardness) such as polypropylene, PTE, Dupont Hybrid, Hytrel, Ritaflex, opaque ribs, translucent film, or combinations thereof) or may be formed separately from the tube portion **5072** and attached thereto (e.g., glued, welded). In an embodiment, the end fittings **5074** may be overmolded to respective ends of the tube portion **5072**.

As best shown in FIGS. **20-2** and **20-4**, each end fitting **5074** includes a sealing lip **5075.1** at its free end, an annular flange **5075.2** that provides a snap feature, and one or more annular ribs **5075.3** (e.g., two ribs) that provide finger grips.

Swivel Attachment

The swivel **5090** (e.g., constructed of a hard plastic material such as polypropylene, Hytrel, HTPC) includes a first portion **5092** adapted to connect to the short tube **5070** and second portion **5094** adapted to connect to an air delivery tube.

As shown in FIGS. **20-2** to **20-4**, the first portion **5092** provides diametrically opposed windows **5095.1** through the swivel side wall and an inwardly facing tapered surface **5095.2**. The second end portion **5094** provides a tapered side wall for connection to the air delivery tube. Also, spaced apart flanges **5096** are provided to the swivel **5090** which defines a space therebetween for a tube retainer clip adapted to retain the air delivery tube.

The end fitting **5074** of the short tube **5070** is structured to engage the first portion **5092** of the swivel **5090** with a snap or press fit, i.e., annular flange **5075.2** resiliently deflects into windows **5095.1**. In addition, the sealing lip **5075.1** of the end fitting **5074** resiliently deflects into engagement with the inwardly facing tapered surface **5095.2** to provide an interference fit for sealing around the interior perimeter of the swivel. The first portion **5092** of the swivel **5090** also includes cut outs **5098** (see FIGS. **20-2** and **20-3**) to provide finger clearance to facilitate assembly/disassembly of the end fitting **5074** to the swivel **5090**.

In an alternative embodiment, the swivel may be overmolded to an end fitting of the short tube, e.g., to reduce the number of components, size, etc. In other alternatives, the swivel may be bonded with glue or welded to the end fitting.

Elbow Attachment

The other of the end fittings **5074** of the short tube **5070** is attachable to the elbow **5040** in a similar manner as the swivel **5090**. Specifically, as shown in FIG. **17**, the end fitting **5074** of the short tube **5070** is structured to engage the second portion **5044** of the elbow **5040** with a snap fit, i.e., annular flange **5075.2** resiliently deflects into windows **5046** (see FIGS. **18-1** and **18-3**). In addition, the sealing lip **5075.1** of the end fitting **5074** resiliently deflects into engagement with the inwardly facing tapered surface **5048** to provide an interference fit for sealing around the interior perimeter of the elbow. The second portion **5044** of the elbow **5040** also includes cut outs **5049** (see FIGS. **18-1** and **18-3**) to provide finger clearance to facilitate assembly/disassembly of the end fitting **5074** to the elbow **5040**.

FIGS. **20-5-1** to **20-5-6** illustrate a short tube **5770** with elbow **5740** and swivel **5790** according to another embodiment of the present invention. The elbow **5740** (described above in reference to FIGS. **18-8-1** to **18-8-7**) and swivel **5790** may be attached to respective ends of the short tube **5770**, e.g., by friction fit, mechanical interlock, and/or overmolding. In the illustrated embodiment, a small bore tube adaptor **5791** is provided to the short tube for coupling the swivel **5790**, e.g., adaptor provides barbed connection.

The short tube includes one or more of the following functions: connects the air supply to the patient interface from the flow generator within an acceptable level of impedance level as specified by system requirement; reduces forces that may de-stabilize the mask and sealing because of the tube drag that weight of the flow generator tube and tangling of this tube may cause; reduces visual and physical obtrusiveness of the overall mask size; the inside of the tube is smooth to minimize generating noise due to air turbulence; the stiffness of the tube shall be sufficient to prevent kinking or stretched under normal usage conditions; tube fittings shall not have any smell; the tube shall have thermal insulation properties to reduce condensation build-up or "raining" in the tube; aesthetically pleasing and reflect high quality and style; the tube should be easy to assemble/disassemble from the mask; total leak in the short tube assembly should not cause the total mask flow to be outside the specified flow limit; the tube end fitting should have a finger grip area, an area that can hold on to during assembly and disassembly of the tube from the elbow or from the swivel.

In an embodiment, the length of the tube is about 200-400 mm, e.g., 300 mm, the elbow to tube retention is more than about 20N, and the swivel to tube retention is more than about 20N.

The short tube may also include one or more of the following features:

Through Impedance: The through impedance characteristics in the short tube assembly (e.g., short tube and end fittings or connectors) should not cause the mask system impedance to be elevated above acceptable limits. The length and the diameter of the short tube, surface finish inside the connectors and in the short tube, the shape of the elbow fitting, and amount of change in flow direction may be contributing factors that affect the through impedance in the short tube assembly. In addition, the position of the airflow inlet in relation to the nasal prong assembly may contribute to the airflow impedance.

Kinking and Occlusion: The short tube may be sufficiently rigid or constructed to minimize the possibility of kinking when placed over the top of bedrails or through the top of doors of incubators. The short tube may be structured to prevent occlusion when placed in areas around the patient, including when the patient's head or arm is on the short tube. The resistance to kinking and occlusion of the short tube can be based on the material strength of the short tube, the thickness of the short tube walls and the ribs, and the short tube dimensions such as the length, the pitch distance of the helix, and the diameter of the short tube.

Flexibility of the Short Tube: The short tube should be sufficiently flexible to reduce any forces applied to the mask system during any movement of the air tubes. Movement of the short tube towards different elbow positions should not cause extra leakage between the nasal prongs and nasal cavity.

Leakage in the Short Tube Assembly: In an embodiment, the leakage in the short tube assembly is less than 1 L/min @ 20 cmH_2O.

Tube Retention: In an embodiment, the short tube assembly is structured to withstand 30 cmH_2O of pressure for about 12 hours without dislodgment of parts, and the connection of the parts is structured to withstand 20 N of pull force at various angles without fracturing or detaching from the mask elbow (force limit is about double the maximum bearable force which could be applied to person's face).

Swivel Rotational Requirements: The purpose of the swivel is to reduce application of any torsion forces to the mask system when the patient changes sleeping positions. The swivel can rotate through 360 degrees relative to the tube adaptor or lower swivel. In an embodiment, the swivel will not squeak during normal movement of the short tube or the mask system. In an embodiment, the swivel may securely snap-fit onto the lower swivel.

Comfort Factor: The short tube may be structured to optimize comfort when the patient moves during sleep. For example, all the parts in the short tube assembly may have a substantially smooth finish on its outer surface.

Assembly Integrity: In an embodiment, the short tube assembly does not have parts that are likely to catch bedclothes and dislodge the mask system or interrupt the seal.

Biocompatibility: In an embodiment, all short tube components are biocompatible.

Chemical Human Factors: In an embodiment, the tube assembly is easy to assemble and disassemble. For example, the components may be intuitive to assemble and disassemble, and may be fail safe (only able to be assembled in one way) if ends of the short tube assembly have different connection.

Dislodging: The mask system may be structured so that small parts cannot dislodge and be inhaled.

Durability During Use: The short tube assembly (including mask) may be durable or disposable.

In an embodiment, the short tube may have a diameter of about 13-13.5 mm (e.g., 13.5 mm) and a length of about 200-250 mm (e.g., 250 mm). However, other dimensions are possible as noted above.

The short tube may be manufactured from Polyolefin (e.g., which allows the tube to be made transparent), Hytrel (e.g., Hytrel 5556), or Riteflex materials. In an embodiment, the short tube and connectors may be made from a combination of Hytrel or Riteflex material to allow overmolding of the short tube on the connectors.

4 Other Aspects

Patient Interface

FIGS. **1-1** and **2-1** to **2-2** illustrate a patient interface or mask system according to an embodiment of the present invention. As illustrated, the patient interface includes a nasal prong assembly **20** (FIGS. **2-1** to **2-2**) adapted to provide an effective seal or interface with the patient's nose and headgear **50** (FIG. **1-1**) adapted to support the patient interface in a desired position on the patient's head.

Comfort and Seal

Embodiments of the invention are directed towards patient interfaces having structure to provide a comfortable and effective seal with the patient's face. Moreover, embodiments of the invention are directed towards patient interfaces having improved static sealing performance (e.g., the ability to allow lower strap tension from headgear to create a sealing force) and improved dynamic sealing performance (e.g., the ability to withstand macro-movement from a patient rolling around in bed and maintain a seal and/or to withstand changes in the patient's face in the short term (when the face relaxes and the cheeks fill will pressurized air) and in the long term (if the patient's facial features change, e.g., based on weight change, etc.). For example, embodiments of the invention are directed towards patient interfaces having one or more features that, either alone or in cooperation with other features, provide a unit that as a whole allows a range of movement without breaking seal or losing comfort (e.g., patient can sleep on side without dislodging nasal prongs from the patient's nose). Such interface properties are described in greater detail below.

Alternative Patient Interface Embodiment

FIGS. **13-1** to **13-4** and **14-1** to **14-2** illustrate a patient interface or mask system **5010** according to another embodiment of the present invention. As illustrated, the patient interface **5010** includes a frame **5030**, a nasal prong assembly **5020** provided to the frame **5030** and adapted to provide an effective seal or interface with the patient's nose, an elbow **5040** provided to the frame **5030** and adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and headgear **5050** adapted to support the patient interface in a desired position on the patient's head. As illustrated, the patient interface provides a relatively narrow configuration with a central swivel which provides a comfortable interface that allows a range of movement in use (described in greater detail below).

Comfort, Seal, and Allowing Range of Sleeping Positions

As illustrated, the patient interface **5010** provides an arrangement including a low number of components, a relatively small overall size including a relatively small, narrow frame (smaller profile, streamlined, less obtrusive), no seal rings, end caps, or vent caps, relatively thin headgear yokes with reduced obtrusiveness (e.g., less visual obtrusion), easy assembly, enhanced adjustability, and perceivable to be light and small. In addition, the patient interface **5010** provides an arrangement that may be more comfortable for side sleepers and may even allow the patient to be face down while maintaining a seal. For example, the patient interface **5010** allows a range of movement without breaking seal or loosing comfort (e.g., patient can sleep on side without dislodging nasal prongs from the patient's nose).

In an embodiment, as shown in FIGS. **13-2** and **13-4**, the patient interface may include a width W (i.e., width of nasal prong assembly) of about 50-60 mm, e.g., 54 mm, a height H (i.e., height from tip of nasal prong to bottom of elbow) of about 65-75 mm, e.g., 69 mm, and a depth D (i.e., depth from edge of nasal prong assembly to edge of elbow) of about 35-45 mm, e.g., 39 mm. These dimensions are merely exemplary, and other dimension are possible depending on application.

Alternative Systems for Positioning and Supporting Nasal Prongs

FIGS. **31-1** to **45-2** illustrate alternative systems for positioning and supporting a pair of nasal prongs in a patient's nares for the provision of respiratory treatment, e.g., CPAP treatment. Aspects of the invention relate to reducing or minimizing the size of such a system.

For example, in an embodiment, ResMed's Swift mask may be reduced in width by relocating tube lugs on the frame to the inside of the frame, the elbow may be shortened, a seal ring may be added to the port plug or elbow (e.g., o-ring), and the yokes may be connected directly to the frame.

FIGS. **31-1** and **31-2** illustrate a mask system **9510** in which the yoke to frame interface **9585** is extended from the yoke **9555** and connected to a narrowed frame/nasal prong assembly **9520**. As illustrated, a side tube exit is provided, e.g., to reduce the risk of seal compromise through tube drag.

FIGS. **32-1** and **32-2** illustrate another mask system **9610** in which the yoke to frame interface **9685** is extended from the yoke **9655** and connected to a narrowed frame **9630** and nasal prong assembly **9620**. As illustrated, a side tube exit is provided, e.g., to reduce the risk of seal compromise through tube drag. In this embodiment, the yoke **9655** and frame **9630** may be integrally molded as a one piece structure or may be molded as two separate pieces.

FIGS. **33-1** and **33-2** illustrate a mask system **9710** in which nasal prong assembly **9720** is supported by a cradle **9759** provided to the yokes **9755**. Such cradle arrangement reduces mask width by shifting rotational support from the ends of the nasal prong assembly (two locations) to the center of the nasal prong assembly (single location).

FIG. **34** illustrates a mask system **9810** in which a Y-piece inlet tube **9870** is provided to the mask for central mounting. The side tube exits on the mask may reduce the risk of seal compromise through tube drag. Such inlet tube may be used with the yoke to frame interfaces shown in FIGS. **32-1** to **33-2**.

FIG. **35** illustrates a mask system **9910** in which a simple plastic frame **9930** supports or holds silicone molded prongs **9924** provided to an inlet tube **9970**, e.g., prongs inserted through and retained within openings provided to frame. Such arrangement provides a mask system with low part count.

FIG. **36** illustrates a mask system **10010** in which a silicone nasal prong assembly **10020** includes an angular adjustment built into or integrated into the assembly. For example, the nasal prong assembly **10020** may include pins **10021** received in respective openings of the yokes **10055**, e.g., friction fit. A cavity **10023** in respective sides of the nasal prong assembly **10020** allow for a degree of rotation.

FIG. **37** illustrates a mask system **10110** in which a silicone nasal prong assembly **10120** is wrapped around a rigid plastic tube **10130**. The rigid tube **10130** acts as an air path and two holes **10131** in the rigid tube release pressurized air to the nasal prong assembly **10120**. Such arrangement provides a reduction in parts and a reduction in mask width.

FIG. **38** illustrates a mask system **10210** including a rigid inner tube **10230**, a flexible silicone outer frame **10231** provided to the tube **10230**, and nasal prongs **10224** engaged or pushed into the rigid inner tube **10230**. A side tube exit is provided, e.g., to reduce the risk of seal compromise through tube drag.

FIGS. **39-1** and **39-2** illustrate a mask system **10310** including a simple plastic frame **10330** that supports or holds a silicone molded prong interface **10320**. As illustrated, the prong interface **10320** includes pins **10321** received in respective openings of the frame **10330**, e.g., with a friction fit. Also, the prong interface **10320** includes a tube portion **13023** adapted to engage an inlet tube **10370**. The frame **10330** includes openings for engaging respective headgear straps and may act as a rigidizer to headgear straps. Such arrangement provides a mask system with a minimalist design including a low part count and small/narrow footprint.

FIG. **40** illustrates a nasal prong **10424** that is free to rotate or translate along a curved path within a secondary rigid component **10440**. Such prong arrangement may be integrated into one or more of the embodiments described above. In an embodiment, each nasal prong may be independently rotated or otherwise adjusted with respect to the secondary rigid component **10440**.

In another embodiment, the nasal prong assembly may be reduced in width. For example, FIG. **41-1** illustrates a nasal prong assembly **10520** having a width W and FIG. **41-2** illustrates a nasal prong assembly **10620** having a width w which is about 40% less than that of nasal prong assembly **10520**. As shown in FIG. **41-3**, the nasal prong assembly **10620** may be secured in position by wrapping each end **10621** of the nasal prong assembly over a lip **10631** on the frame **10630** and then engaging the yoke **10655** over the end **10621**.

FIG. **42** illustrates a mask system **10710** without a frame. As illustrated, ends of the nasal prong assembly **10720** (e.g., one piece arrangement) are retained by the yoke **10755** which also supports the elbow **10740**.

FIG. **43** illustrates nasal prongs **10824** push-fit to a frame **10830**. In an embodiment, overmolded seal rings **10858** may be provided to ends of the frame **10830**.

FIG. **44** illustrates another embodiment of a mask system **10910** without a frame. As illustrated, ends of the nasal prong assembly **10920** wrap around the yokes **10955** to seal. The nasal prong assembly **10920** may self seal or a clip may provided to facilitate a seal. The elbow or short tube **10940** may be sealed to the yoke **10955** via an o-ring **10941** (e.g., overmolded to the elbow). In the illustrated embodiment, each side of the mask includes an inlet port (i.e., double sided port) in which one side may be blocked off. Alternatively, only one side of the mask may include a port (i.e., single sided port), therefore no plug may be necessary. The side mounted elbow-to-yoke arrangement may improve stability of the mask, e.g., compared to a front mounted elbow-to-frame/nasal prong assembly arrangement.

FIG. **45-1** illustrates a nasal prong assembly **11020** having a central axis A and FIG. **45-2** illustrates a nasal prong assembly **11120** having a central axis a which is shifted to make the prongs longer in the nose to reduce width. This arrangement may also improve comfort by lifting the prongs off the patient's top lip in use. In an embodiment, the mask system may be provided without a frame so that the yokes **11155** support the nasal prong assembly **11120**.

Range of Movement

In an embodiment, the patient interface may be broadly broken down into a pair of nasal prongs adapted to provide an effective seal or interface with the patient's nose and a support arrangement to support the nasal prongs in an operative position on the patient's face. The support arrangement is structured to provide a range of rotational, axial, and lateral movement to the nasal prongs while maintaining a sufficient seal and resisting the application of tube drag and headgear tension to the nasal prongs. In an embodiment, the support arrangement may include everything besides the nasal prongs and even parts of the nasal prongs, e.g., a gusset, a frame, and/or headgear as described above. Thus, the patient interface provides one or more features that, either alone or in cooperation, allow a range of movement without breaking seal or loosing comfort.

While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

What is claimed is:

1. A patient interface for delivering breathable gas to a patient, the patient interface comprising:

a nasal prong assembly including a pair of nasal prongs structured to sealingly communicate with nasal passages of a patient's nose in use; and

headgear to maintain the nasal prong assembly in a desired position on the patient's face, the headgear including first and second side straps and respective rigidizers provided to respective side straps such that each of the respective rigidizers is coextensive with a respective side strap at least along a portion of the headgear configured to extend along a side of the patient's bead, each of the respective rigidizers providing rigidity to a respective one of the first and second side straps,

each rigidizer including a first end portion that provides 1) a connector structured to engage a respective end of the nasal prong, assembly and 2) a protrusion that curves inwardly of the connector and forms a cheek support, the cheek support adapted to follow a contour of the patient's cheek and guide a respective end portion of the side strap into engagement with the patient's cheek to provide a stable cheek support.

2. A patient interface according to claim **1**, wherein the patient interface further comprises a base region and each nasal prong includes a head portion adapted to seal with a respective patient nasal passage and as stalk that interconnects the head portion with the base region.

3. A patient interface according to claim **2**, wherein the bead portion includes a. dual or double-wall arrangement including an inner wall and an outer wall that surrounds the inner wall.

4. A patient interface according to claim **2**, wherein each prong includes an upper trampoline-like suspension system between the head portion and the stalk, and a lower trampoline-like suspension system between the stalk and the base region.

5. A patient interface according, to claim **1**, wherein the nasal prong assembly includes structure to reduce and/or eliminate an air jetting effect.

6. A patient interface according to claim **1**, wherein the cheek support is arranged such that headgear tension is applied to the cheek support rather than to the pair of nasal prongs to prevent the pair of nasal prongs from being compressed.

7. A patient interlace according to claim **1**, wherein each of the respective rigidizers includes rib-strengthened brackets to support the connector on the rigidizer.

8. A patient interlace according to claim **1**, wherein the headgear includes a rear strap that passes around a rear portion of the patient's head.

9. A patient interface according to claim **8**, wherein each of the respective rigidizers includes a slot that defines a cross-bar adapted to engage a respective end of the rear strap.

10. A patient interface according to claim **1**, wherein each of the respective rigidizers is attachable to a respective side strap via stitching, welding, and/or gluing.

11. A patient interface according, to claim **1**, wherein a width of the side strap on at least one side of the rigidizer is about 5-9 mm.

12. A patient interface for delivering breathable gas to a patient, the patient interface comprising:

a nasal seal to sealingly communicate with the patient's nose in use and headgear to maintain the nasal seal in position on the patient's face, the headgear including side portions,

each of said side portions including a side strap and a rigidizer provided to the side strap, each rigidizer including a main portion and a curved protrusion branching off from the main portion and terminating in a free end, the curved protrusion thereby forming a cheek support configured to Mow a contour of the patient's cheek and guide an end portion of each respective side strap into engagement with the patient's cheek to provide a stable cheek support,

wherein the cheek support is configured to flex relative to the main portion in order to conform to the contours of the patient's cheek.

13. A patient interface for delivering breathable gas to a patient, the patient interface comprising:

a nasal prong assembly including a pair of nasal prongs structured to sealingly communicate with nasal passages of a patient's nose in use;

a frame configured to support the pair of nasal prongs; and

headgear connectable to the frame to maintain the frame and the nasal prong assembly in position on the patient's face, the headgear including left and right side straps formed of soft, flexible material and respective rigidizers formed of semi-rigid material attached to the respective left and right side straps to provide rigidity to the left and right side straps,

wherein each of said respective rigidizers includes a main portion and an end portion, the end portion branching off from the main portion in two directions to form. respectively, 1) a connector configured to connect the rigidizer to a respective end of the frame and 2) a flexible cheek support terminating in a free end and being configured to disperse headgear tension across the patient's cheek such that headgear tension is applied to the flexible cheek support instead of the nasal prongs.

14. A patient interface according to claim **13**, wherein each flexible cheek support is configured to follow the contour of the patient's cheek and guide a respective end portion of the side strap into engagement with the patient's cheek.

15. A patient interface according to claim **13**, wherein each flexible cheek support is configured to disperse headgear tension below the patient's cheek bone.

16. A patient interface according to claim 13, wherein each flexible cheek support extends from the respective rigidizer as a cantilever.

17. A patient interface according to claim 13, wherein the left and right side straps are elastic.

18. A patient interface according to claim 13, wherein the frame comprises an aperture between the respective ends of the frame that is configured to receive a flow of breathable gas.

19. A patient interface according to claim 13, wherein each connector is supported on the respective rigidizer by brackets.

20. A patient interface according to claim 19, wherein the brackets comprise ribs that increase rigidity of the connector.

21. A patient interface according to claim 19, wherein the flexible cheek support is provided between the brackets.

22. A patient interface according to claim 1, wherein each rigidizer includes a second end portion connected to a main portion of the rigidizer.

23. A patient interface according to claim 22, wherein both the first and second end portions are located at opposing ends of the respective rigidzer.

24. A patient interface according to claim 23, wherein the second end portion is configured to be connected to a strap.

25. A patient interface according to claim 12, wherein the protrusion curves inwardly from the side strap toward a front of the patient's face.

26. A patient interface according to claim 25, wherein a connector branches off from the main portion of each rigidizer and is configured to connect the riuidizer to a frame which supports the nasal.

27. A patient interface according to claim 13, wherein the flexible cheek support terminates at a location away from the main portion of the rigidizer.

28. A patient interface according to claim 1, further comprising a pad provided to each of the respective rigidizers and adapted to contact a side of the patient's face, wherein the pad includes foam.

29. A patient interface according to claim 12, further comprising a pad provided to the rigidizer and adapted to contact a side of the patient's face, wherein the pad includes foam.

30. A patient interface according to claim 12, wherein each rinidizer is coextensive with the respective side strap at least along a portion of the headgear configured to extend along a side of the patient's head, the rigidizers providing rigidity to the first and second side straps.

31. A patient interface according to claim 13, further comprising a pad provided to each of the respective rigidizers and adapted to contact a. side of the patient's face, wherein the pad includes foam.

32. A patient interface according to claim 13, wherein each rigidizer is coextensive with a respective side strap at least along a portion of the headgear configured to extend along a side of the patient's head.

33. A patient interface according to claim 12, wherein the free end of the curved protrusion is configured to be positioned on the patient's cheek when the patient interlace is worn.

34. A patient interface according to claim 13, wherein the free end of the flexible cheek support is configured to he positioned on the patient's cheek when the patient interface is worn.

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